

**IMPROVING UPPER EXTREMITY MYOELECTRIC
PROSTHESIS FUNCTIONALITY THROUGH THE USE
OF INTRAMUSCULAR EMG SIGNALS**

by

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Abstract

The prevalence of upper extremity amputation is increasing in the United States. To meet the demand of decreased functionality associated with upper extremity loss, prosthetic design has become increasingly complex, allowing for an high number of operable degrees-of-freedom (DOFs). Unfortunately, the ability to control this increased mechanical capability is limited. Pattern recognition using EMG signals obtained from surface electrodes is the state-of-the-art for myoelectric prosthetic control; however, it is limited in its ability allow for natural, simultaneous control of multiple DOFs. Recognizing this limitation, some researchers have focused efforts on creating control algorithms based on intramuscular signals. Despite initial reports that demonstrated no improvements in the classification accuracy, more recent literature presents intramuscular EMG signals as potentially useful drivers of classifying multiple, simultaneous DOFs. As opposed to surface-based signals, intramuscular signals are generated from a much smaller conduction volume, dependent on the type of electrode used. A novel combined control strategy incorporating both intramuscular and surface EMG signals may have the potential to leverage advantages from

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both strategies.

The research presented herein represents the first examination of complementing the more global signal obtained from surface electrodes with the muscle-specific information from intramuscular electrodes. When compared to control with either intramuscular or surface signals alone, a strategy involving combining information from both signal sources results in the highest degree of classification accuracy for controlling wrist rotation, flexion and hand grasps simultaneously using a 3-DOF LDA classifier. A single classifier, in which 3 DOFs are included, outperformed a parallel classifier, in which each DOF was independently classified and all classifications combined for a single 3 DOF output. However, high classification accuracies for each individual DOF highlight the potential for using combined signals for accurate control of a prosthetic limb. The impacts of these findings are also discussed, including the implication for future prosthetic and electrode design. Additionally, a novel method for quantitatively measuring the functionality of a prosthetic user is included.

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Secondary Reader: Marlis Gonzalez-Fernandez, M.D., Ph.D.

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Dedication

This thesis is dedicated to all upper extremity amputees who have dedicated their time and effort to improve prosthetic capabilities. Theirs' are the shoulders upon which the field firmly rests.

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Chapter 1

Introduction

Loss of an upper extremity has dramatic detrimental effects, most notably the loss of functional capability and associated emotional, psychological and physical sequelae. Advances in myoelectric prosthesis technology have allowed for the creation of limbs with multiple degrees of freedom with the possibility to return function to the user. Unfortunately, this goal has yet to be realized due to insufficient control algorithms. One component of this problem relies on the method of signal acquisition, namely, electromyographic signals, and the inherent noise in their decoding. Therefore, the goal of this research is to create a control mechanism for use with myoelectric upper extremity prostheses that will allow for simultaneous control of multiple degrees of freedom around the wrist and hand. This first chapter will introduce the current state of prosthetics in upper extremity amputations. In doing so, it will discuss the current methods of control using surface electromyography, highlighting the benefits

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and limitation of this approach. I will also highlight the factors affecting users' decisions to not use their prostheses. In doing so, I will clearly establish the need for an improved method of prosthetic control using a physiologically-based methodology, such as intramuscular electromyography, and will inform the specific aims of the research performed for this thesis.

1.1 Upper Extremity Amputation

1.1.1 Prevalence and Burden of Disease

Upper extremity amputation is a devastating injury that commonly results in significant functional and emotional impairments. Review of the National Inpatient Sample (NIS) database, a nationwide database that represents 20% of the hospitalized patients in the United States, estimated approximately 41,000 patients with major upper extremity amputation in 2005.¹⁷ This prevalence is expected to continue to rise.¹⁸ Across all populations, trauma accounts for nearly 92% of upper extremity amputations.¹⁷ The conflicts in Iraq and Afghanistan have demonstrated an increase in the number of amputations seen among service members, and, as of July 2011, 270 major upper extremity amputations had been performed for military personnel serving in Operations Enduring Freedom and Iraqi Freedom.^{19,20} Due to the requirements of active duty service, amputation among service members affects a population with relatively few comorbidities. Even among the civilian population, patients who

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suffer upper extremity amputation tend to be younger and otherwise healthy.²¹ Less common causes of amputation include vascular disease, malignancy and congenital malformation.²² Amputation of the hand or wrist represents approximately 90% of major upper extremity amputations and will be the focus of this research.²²

Upper extremity amputation has a strong negative impact on psychosocial and functional outcomes over the course of the patient's lifetime. Among civilian amputees, only 40% of amputees are employed.²³ Affected active duty service members reported an even lower rate (16.5%) of return to active duty following traumatic upper extremity amputation.²⁴ Causes of unemployment following amputation are multifactorial and represents not only the obvious functional limitation imposed by loss of an upper extremity, but also emotional burden of limb loss. In fact, symptoms of clinical depression are present in between 21-35% of all amputees.²⁵ Psychologic illness can itself significantly reduce post-amputation functionality. Post-traumatic stress disorder (PTSD) is the most common cause of non-amputation related disability among upper extremity amputees.²⁶ Further, studies of memories of amputation-related events found them to be as vivid as much more recent memories, regardless of their temporal proximity.²⁷ The goal of an upper extremity prosthetic is to mitigate either one or both of these adverse impacts of limb loss.

1.1.2 Anatomy of the Upper Extremity

Design and control of any upper extremity prosthesis requires an understanding of the anatomy of the forearm, specifically the muscles of the forearm and their function on affecting movement at the wrist or hand. The muscles of the forearm can be typically divided into two groups based on their anatomic relationships (anterior or posterior) or functionality (flexion or extension). Fortunately, these two designations tend to overlap, such that muscles within the posterior compartment of the forearm act as extensors whereas muscles with the anterior compartment of the forearm function as flexors of the wrist or fingers (Figures 1.1 and 1.2). This “geographic” grouping of muscles has implications when designing control mechanisms in the upper extremity amputee. Another important concept is the antagonistic interaction of these muscle groups based on their function and location. Muscles within opposite groups tend to exert antagonistic actions to one another. Muscles of the forearm also demonstrate close proximity and functional interaction, such as co-contraction, a reality that significantly affects control of upper extremity prostheses. Indeed, many muscle groups of interest actually physically overlies each other altogether.

1.1.2.1 Muscles of the Forearm

The flexor muscles are housed within the anterior compartment of the forearm and control flexion of the wrist and fingers, which allow for important grasping movements. The major flexor muscles of the fingers and thumb are the *flexor digitorum*

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superficialis, *flexor digitorum profundus* and *flexor pollicis longus* (Figure 1.1). The muscles of wrist flexion are *flexor carpi radialis* and *flexor carpi ulnaris*. In addition to these muscles of flexion, there are also two muscles that actuate pronation of the wrist, the *pronator teres* and *pronator quadratus*.

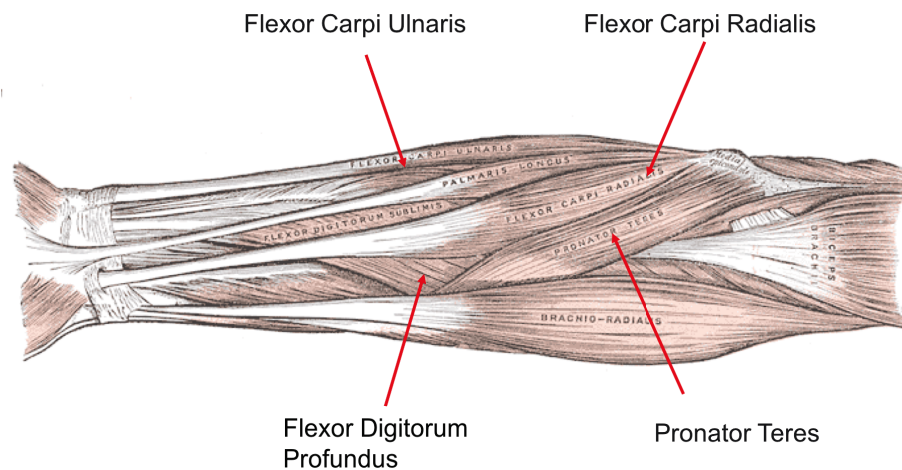


Figure 1.1: Flexor Anatomy of the forearm demonstrating the major muscles of hand flexion (*flexor digitorum profundus*) and wrist (*flexor carpi ulnaris*). The flexor anatomy of the forearm is composed of the muscles on the ventral aspect of the forearm that are housed within the anterior compartment. In general, these muscles are responsible for closing the hand and flexing the wrist. The specific muscle functions are described in table.¹

The posterior compartment of the forearm contains the extensor muscles of the wrist and fingers, as well as the *supinator*, which controls supination of the hand at the wrist. The major extensor muscles that function to open the hand are the *extensor digitorum communis*, *extensor pollicis longus/brevis* and *extensor digiti minimi* (Figure 1.2). The wrist is extended through the action of the *extensor carpi radialis longus/brevis* and *extensor carpi ulnaris*. As mentioned previous, the supination function of the wrist is performed by the *supinator*, located deep with the posterior

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compartment.

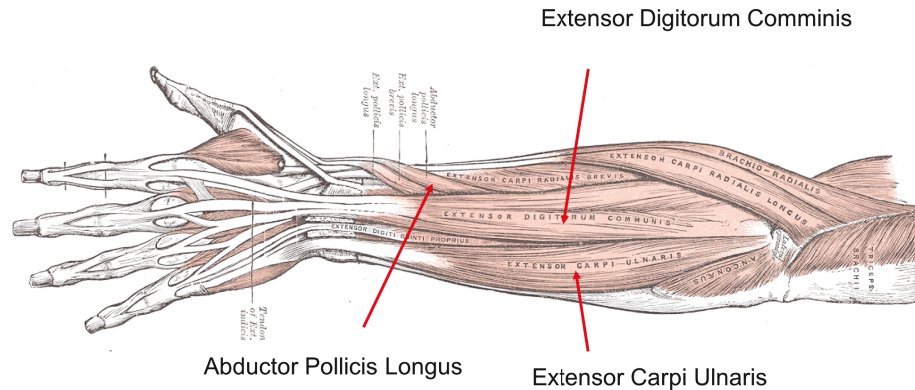


Figure 1.2: Extensor muscles of the forearm including the major muscle of finger extension (extensor digitorum communis) and multiple muscles of wrist extension. Extensor muscles of the forearm are on the dorsal aspect of the arm within the posterior compartment. Muscles within the posterior compartment have the general purpose of extending the wrist and the fingers. The specific muscles for extension are included in the table.¹

Even within individual compartments (anterior or posterior), muscles of flexion and extension control different joints depending on their insertion sites. The table provided below helps to summarize the compartmental location and function for the major muscles of the forearm (1.1). Of note, during a major operation, surgeons attempt to maintain as much forearm length as possible, often mid- to distal forearm. Many of the muscles listed have proximal insertion sites at or very near the elbow and therefore are likely to be preserved in the transradial amputee population.

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Muscle	Compartment	Function
Flexor Digitorum Profundus	Anterior	Wrist Flexion, Metacarpal Flexion
Flexor Digitorum Superficialis	Anterior	Finger Flexion
Flexor Pollicis Longus	Anterior	Thumb Flexion
Flexor Carpi Ulnaris	Anterior	Wrist Flexion, Medial Deviation (Adduction)
Flexor Carpi Radialis	Anterior	Wrist Flexion, Lateral Deviation (Abduction)
Pronator Teres	Anterior	Wrist/Forearm Pronation
Extensor Digitorum Communis	Posterior	Wrist Extension, Finger (not Thumb) Extension
Extensor Pollicis Longus	Posterior	Thumb Extension
Extensor Carpi Ulnaris	Posterior	Wrist Extension, Medial Deviation (Adduction)
Extensor Carpi Radialis	Posterior	Wrist Extension, Lateral Deviation (Abduction)
Abductor Pollicis Longus	Posterior	Extend (Abduct) Thumb at Wrist
Supinator	Posterior	Wrist/Forearm Supination

Table 1.1: Forearm muscle locations and actions.

1.2 Prosthetics in Upper Extremity Amputation

The human hand is conventionally classified as having 23 independent degrees-of-freedom (DOFs) and inclusion of the wrist movements expands the available DOFs up to 29.²⁸ Most of the functions used on a daily basis involve variation on grasps (e.g. opening and closing the fingers) and wrist rotation.²⁹ Much of the functionality relies on coordinated finger movement. Appropriately, the designs of upper extremity prostheses have sought to emulate basic finger movements in attempts to restore improved functionality to the user. Prosthetics may be body-powered (driven through a system of cables and pulleys) or externally powered. Body-powered systems rely on movement around remaining joints (elbow or shoulder) and the chest to actuate movement in the limb (Figure 1.3). The terminal end is typically fitted with a hook to allow for environmental manipulation. These represent the earliest “powered”

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prosthetic devices and their creation was largely driven by amputations resultant from the first and second World War.³⁰ While lighter, simpler and highly durable, it is clear that body-powered systems lack the sophistication necessary to recapitulate advanced DOFs of the upper extremity. Further, much of the recent work with improved control mechanisms has been completed for use with myoelectric prosthetic limbs. Therefore, discussion here will be focused on externally-powered, myoelectric prosthetic limbs. Briefly, this section will examine the history of upper extremity prosthesis design and current patterns of usage among upper extremity amputees.

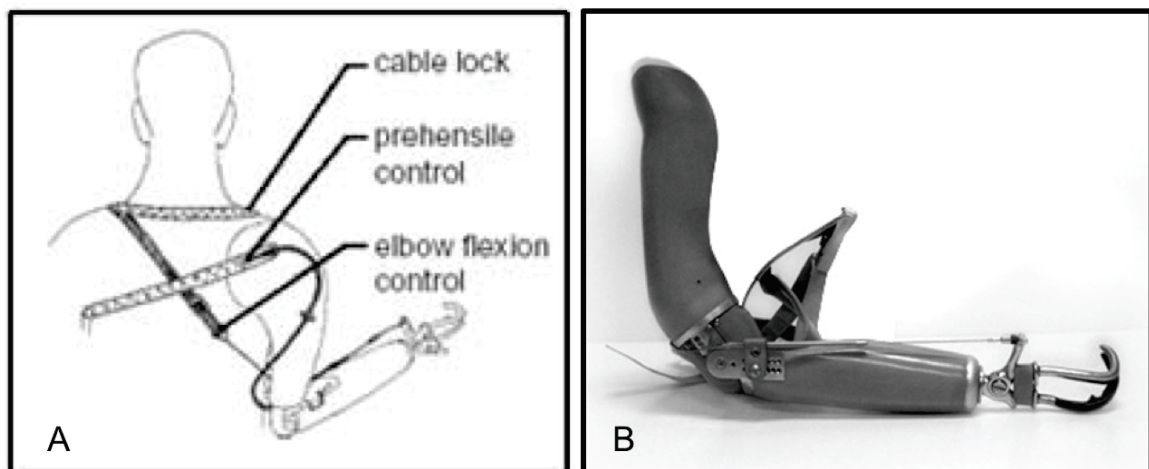


Figure 1.3: Body-powered prosthetic upper extremities are affixed to the user with a harness (A) that connects the movement of an intact shoulder or contralateral limb to the open and close movement of the prosthetic hand. The prosthesis and terminal device (B) most commonly allow for simple open and closed movements.

1.2.1 History of Powered Prostheses

The first documented externally-powered upper extremity prosthesis was developed in Germany in 1915.² It was a hand prosthesis utilizing pneumatic pistons for

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dextrous finger control. However, politic tensions within a post-war Germany and Europe prevented much of the necessary development of the device for widespread use. Further, this devices was expensive and likely not widely available for use. Dr. Reinhold Reiter advanced the field with his introduction of a myoelectric hand in 1948, while a physics student at Munich University.³¹ The prosthesis was not portable owing to the large vaccuum-tube required for their operation. However, despite its development having taken place nearly 70 years ago, it did have similar control patterns to upper extremity limbs used today, and even used electromyograph signal from a single muscle for control.³¹ Another boom in myoelectric prosthetic design occurred in the decades following World War II. In the late 1940s, scientist in Germany developed the Vaduz hand, a single function prosthetic hand for hand open and close, and serves as the inspiration for the current line of Otto Bock hands.³² Movement around additional joints was introduced in the 1960s with the SVEN hand, which incorporated wrist rotation and wrist flexion, as well as hand open and close (Figure 1.4).³³

In the United States, prosthetic design moved from the defense-funded laboratory setting to the commercial landscape in the 1960s. Much of the focus of commercial development, both then and now, involved making these limbs realistic options for daily use. In this regard, the upper extremity prosthesis has made significant strides in the arenas of portability and level of dexterity. Power was provided by nickel-cadmium batteries instead of piston-drive steam power.³⁴ Significant advances in synthetic cov-

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erings led not only to an improvement in aesthetic design, but also greater protection of underlying circuitry, contributing to improved durability. Despite all these advances, however, the control mechanisms have remained largely unchanged and still rely heavily on an EMG-based strategies.

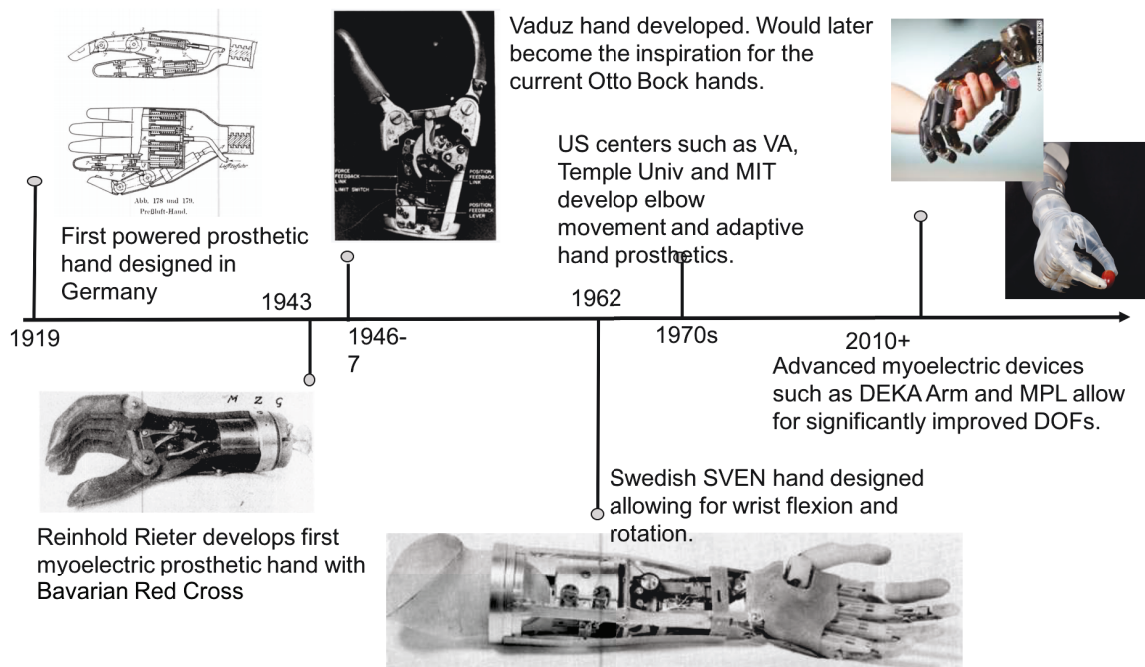


Figure 1.4: Pneumatic powered prosthetics were originally described in 1919 in a post-World War I Germany. The introduction of myoelectric-based movement would come later in 1940s with the introduction of the Vaduz hand. Development during the subsequent decades allowed for incorporation of additional DOFs. Today, advanced prostheses have a similar number of DOFs as the intact human hand. These advanced designs now require advanced control algorithms to utilize their full functionality.²

Current development of advanced prosthetic devices has seen a resurgence since the early 2000s. With the increase in amputations among service members in Operations Enduring Freedom and Iraqi Freedom, the US government has sought to spark innovation in the field of upper extremity amputation and prosthetic design.

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Therefore, the Revolutionizing Prosthetics Program was created through the Defense Advanced Research Project Agency (DARPA) in 2006 to drive this process. Through this funding, the Johns Hopkins University Applied Physics Lab (JHU-APL) has worked to create the Modular Prosthetic Limb (MPL) (Figure 1.5B). In its current phase (Phase 3), the MPL has 26 articulating joints, with 17 controllable DOFs.³ Further, the arm, including hand and battery, weighs approximately 10.5 pounds, consistent with the weight of an intact upper extremity.³ However, with such increased DOFs, control mechanisms have become important for the proper utilization of the limb and therefore limit its current widespread implementation.

Another early product of the Revolutionizing Prosthetics Project with the DEKA arm, created by DEKA Integrated Solutions Corp. (Manchester, NH)(Figure 1.5A). Like the MPL, it has increased DOFs compared to many commercially available prostheses, and, unique to DEKA, provides preprogrammed grip patterns and tactile sensor feedback in the form of vibrations applied to the residual limb.²⁰ User perception tests among Veterans Affairs study groups demonstrated a number of positive feedback comments regarding grip functionality and weight/size acclimation.³⁵ However, there were still ongoing complaints regarding concerns with using the arm near face or head and the cumbersome nature of the incorporated foot control systems.³⁵

These two systems represent the state-of-the-art with myoelectric prostheses. Both offer multiple DOFs with the potential for dexterous, natural movement around the elbow, wrist, and with grips. While they have made observable strides in terms

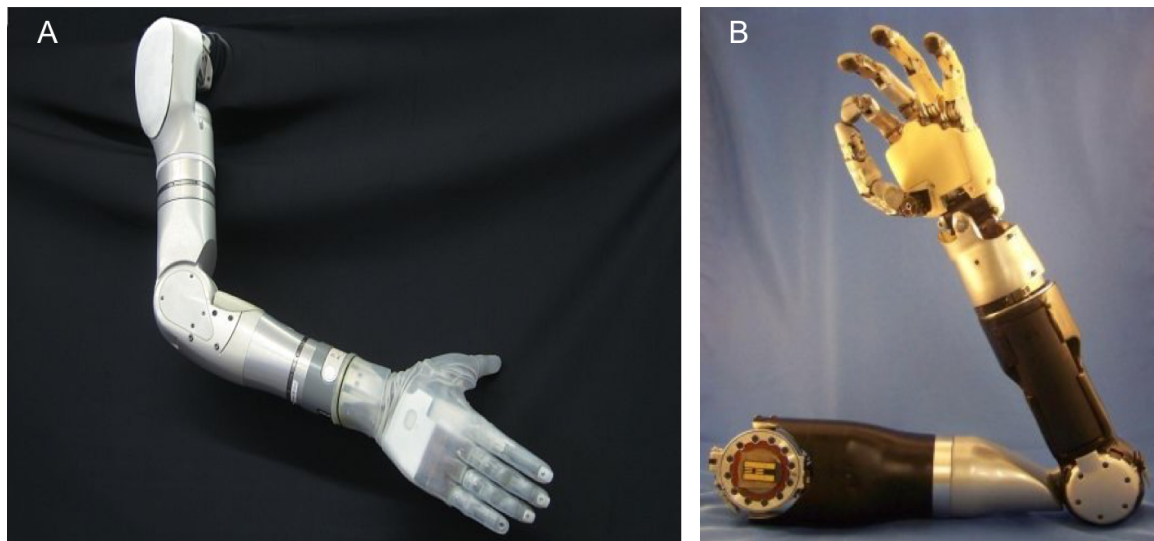


Figure 1.5: The DEKA Arm (A) and MPL (B) represent the cutting edge of advanced prosthesis design. Each aims to replace the full functionality of a missing extremity through elbow movements, wrist movements, and full, dexterous finger movements. The DEKA arm utilizes a combined strategy of EMG and foot pedal to enable control whereas the MPL currently uses EMG and, in some cases, intracortical signals from electrodes on or near the brain.³

of weight, size and portable power supplies, both systems are still waiting for an appropriate control algorithm to maximize functionality and, hence, usability. It is incumbent upon the scientific community to address these control needs, as well as other factors affecting patients' decisions to abandon the use of their upper extremity prosthesis, in order to provide meaningful use of these technologically advanced limbs.

1.2.2 Current Use Patterns

The acceptance rate for upper extremity prosthesis among upper extremity amputees is arguably lower than would be expected for such a debilitating injury. Rejection rates of 40% have been reported.^{36,37} Several factors affecting the decision to

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not wear a prosthesis are patient-level demographics. Female patients are less likely to wear their prosthesis when compared with male patients matched for amputation level and mechanism (39% rejection vs 23% for males).³⁸ Patients with transradial amputations have the lowest rates of prosthesis rejection.³⁸ Finally, patients that rejected their prosthesis were more likely to have a lower perceived “need” for their prosthesis than wearers.³⁸ Using multivariate analysis, Biddis et al determined a significant impact of the time to prosthesis fitting on eventual acceptance, with fitting within 6 months of acquired amputation having a strong correlation to overall acceptance rates.³⁹

Beyond patient-specific factors affecting prosthesis acceptance and use, there are many hardware and software level factors that affect prosthetic use. Many amputees report wearing the prosthesis simply for the purpose of cosmesis, with little impact on their ability to perform activities of daily living (ADLs).⁴⁰ Even among a cohort of patients reporting high overall rates of wearing their prostheses, the prosthetic was used in only half of ADLs.⁴¹ One factor causing low acceptance rates may be related to the comfort of the prosthesis fitting. Among a trauma population with reportedly high prosthetic usage, over half the users reported being dissatisfied with their prosthesis’s comfort.⁴² The size and weight restrictions imposed by user demands for more life-like limbs may have some role in the current limitation of processing power required to control multiple DOFs as well.⁴³ This highlights the difficulties in balancing demand for improved current control mechanisms and results from focus groups regarding

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desire for improvement in cosmesis and weight.³⁷ Further, patterns of low prosthetic usage may propagate depressive symptoms among the upper extremity amputation problem, possibly through a feedforward mechanisms related to an overall decrease in functionality.⁴⁴ Therefore, a strong need exists to expand the current usability of powered upper extremity prostheses to improve patient functionality and overall quality of life, while providing for designs that allow for a more natural user interaction with the prosthesis.

1.3 Electromyographic Control of Prosthetic Limbs

Electromyography is the study of the electric signals of muscles. It references a collective process encompassing the acquisition of the electric signals of muscles, the analysis of that data and the subsequent display of that information.⁴⁵ Electromyography can be used to aid in the diagnosis of neuromuscular, neurodegenerative and primary myopathic diseases. The collection of electrical signals from and electromyography study constitutes the electromyogram (EMG). Because an EMG represents the electrical activity of the underlying muscle, which result from nerve impulses generated in the brain, it can be a useful tool for decoding the “intended” movements of an amputee, even after the limb has been removed. The patterns of electrical signals that make up the EMG can be collected primarily in multiple different ways,

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including through the use of surface or intramuscular electrodes. This section will provide an introduction into the techniques of electromyography for control of upper extremity myoelectric prostheses for patients with these amputations, specifically highlighting the components of EMG signals, methods of signal detection and computational methods for decoding intended movements. With this background, this section will also discuss motivation behind research focusing on intramuscular EMG signals.

1.3.1 Components of EMG Signals

EMG signals are measurements of electric potential over time that represent the recruitment of muscle tissue from the nervous system. The amplitude of the signal is measured in millivolts (mV) and plotted on a two dimensional graph with time as the independent variable (Figure 1.6). The electric signals being detected correspond to the action potentials generated with the activation of each muscle cell within a muscle fiber. Collectively, these action potentials sum up to create a “Motor Unit Action Potential (MUAP).”⁴ The MUAP, therefore, represents the response of communication from the nervous system via peripheral nerves to the muscles with the intent of eliciting an action. As such, its detection, recording and analysis hold potential for the ability to accurately determine intended movement and subsequently translate those into actuated movements with a myoelectric prosthetic limb.

There are several properties of the MUAP that make it a suitable mechanism

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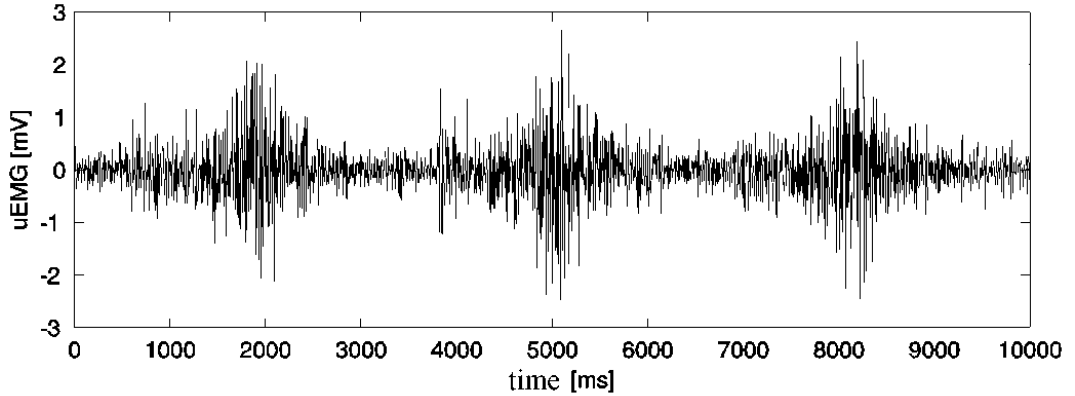


Figure 1.6: Raw EMG Signal for surface EMG recordings from a rectus femoris muscle during voluntary contraction. Signal is measured in mV and plotted over ms. The observed spike and variability are typical of a EMG recording and reflect the recruitment of the target muscle by the nervous system through the propagation of electric signals.⁴

for informing the complex actions of a myoelectric prosthesis. The MUAP can be analyzed for “amplitude, duration, number of phases (changes in direction), and firing rate” to determine certain characteristics of the underlying muscle fiber.⁴⁶ A strong correlation with the mean amplitude (often termed mean absolute value, or MAV) of the EMG signal and the force of muscle contraction exists.^{47–49} Information from firing rate and MAV amplitude may allow for more complex, graded hand movements beyond “full open” or “full close” commands. Signal decomposition by advanced algorithms may allow for even further discrimination of intended movements. One such method, termed k-means clustering, establishes patterns within the EMG signal and has even been used to accurately determine the input pulse train leading to certain EMG signals, helping to visualize even the neuronal input contributing to a muscle contraction.⁵⁰ Decoding more granular components of EMG electric signal,

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such as MAV and firing phase, into meaningful aspects of an intended movement has become the primary focus of most EMG-based prosthetic control research facilities.

An important part of EMG recordings is the noise generated during signal acquisition. Recognition and management of EMG-signal noise is important since it can compromise the ability to interpret user intention based on the EMG signal. Noise can result from user-related factors, such as tissue composition beneath the electrode and body temperature, as well as systems-based “inherent” noise.⁵¹ Different techniques for EMG signal acquisition (e.g. surface-based versus intramuscular) result in different levels of “inherent” noise. The interface between electrode and skin with surface-based recording systems can result in significant noise, and current Ag/AgCl systems are the most-widely used for their ability to balance input impedance and electric stability.⁵² Low frequency noise ($1 - 10Hz$) may also result from motion artifacts created by the movement of muscles beneath the skin-electrode interface.⁵¹

Signal “crosstalk” deserves special consideration in this discussion of EMG-signal components. Crosstalk refers to the phenomenon in which electric signals from active muscles are recorded from electrodes overlying non-active muscles.⁵³ Intuitively, this can lead to misclassification of active muscles when attempting to develop an EMG-based control system for a myoelectric prosthetic. Several factors may affect the degree of crosstalk within the EMG signal. Physiologic factors, such as the amount of subcutaneous adipose tissue, have a role in the amount of crosstalk observed.^{54,55} With regards to signals obtained from surface based electrodes, underlying tissue

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heterogeneity (i.e. bone, fascia, fat, etc) may influence the propagation of muscle signals, resulting in non-linear attenuation and potential crosstalk.^{56,57} Crosstalk has the potential to negatively affect the ability to decode intended muscular movements for control of a myoelectric prosthetic limb, especially with the utilization of increasing DOs. However, within some systems, the additional signal may allow for patterns to be used for classifying movements, even if the signal itself does not represent activation of the intended muscle. Crosstalk is handled differently depending on the method of signal acquisition, a point that will be discussed more thoroughly in subsequent sections.

1.3.2 Methods of Signal Acquisition

Surface-recorded EMG (sEMG) utilizes skin surface-based electrodes to record underlying muscle signals. In this method, Ag/Ag-Cl electrodes are affixed to the skin and serves as the detection mechanism for the underlying EMG signals. Most systems consist of a band of electrode pairs placed circumferentially around the arm. While it may seem that incorporating more electrodes allows for better signal capture, Hargrove et al have demonstrated improved classification accuracy with current algorithms when fewer electrodes are used.⁵ The current research standard is 8 electrode pairs placed circumferentially, equidistant apart, around the thickest part of the forearm. Traditional sEMG systems used simple thresholding techniques to determine intended movements. However, as the abilities of the prosthetic devices improved, the

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need for more complex decoding algorithms arose. *Pattern Recognition* algorithms have been designed to determine patterns in electrical signal that arise when attempting an intended movement. Using pattern recognition systems, high levels of decoding accuracy has been achieved with one and two DOF prosthetics using sEMG.⁵⁸

As mentioned previously, sEMG systems have the potential for multiple sources of signal noise, which may limit the ability to decode higher DoF movements. Signal noise can arise from the interface itself. Sweat at the electrode-skin interface can degrade signal quality and electrode shift during a day or even movement can alter the location of specific electrodes and make it difficult to interpret intended movements. Additionally, signal crosstalk can be commonly seen in surface-based EMG systems. The impact of crosstalk can be seen in the signal correlation charts comparing electric signals detected at different electrode locations (Figure 1.7).⁵ However, this global information may have a positive impact in newer pattern-recognition based systems by providing additional data by which a pattern can be generated. Signal crosstalk and muscle selectivity may be mitigated by placement of electrodes at certain positions along the muscle.⁵⁹ However, no practical way to consistently implement such a placement strategy has been derived and signal crosstalk continues to affect surface-based signals. Currently, signal noise and crosstalk make it difficult to encode three or more DOF movements about the wrist and the hand simultaneously.

An additional method of signal acquisition uses electrodes that sit within or very-near the muscles themselves and is termed intramuscular EMG (iEMG). These “di-

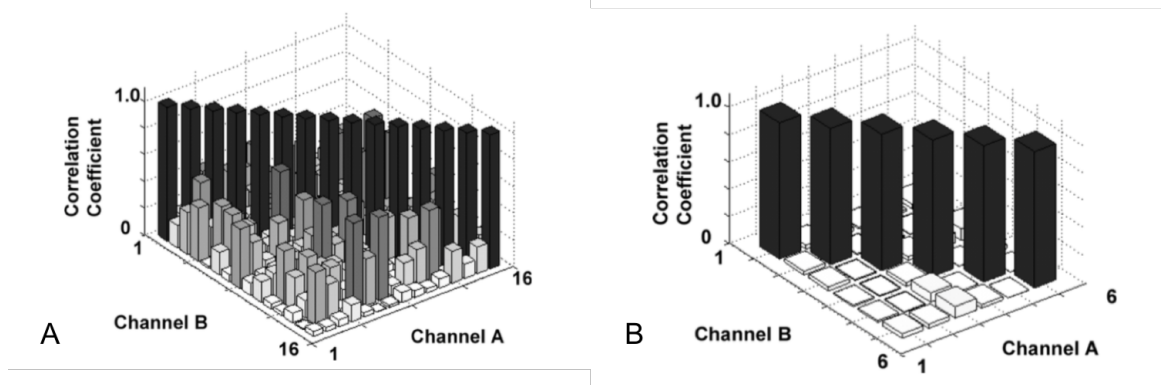


Figure 1.7: Examining the crosstalk with surface (A) and intramuscular (B) EMG signals. Height of the columns indicates degree of correlation. For surface electrodes (A), 16 electrodes are placed concentrically around the forearm. Intramuscular (B) electrodes were placed within 6 muscles of the forearm. Signals with high correlation from opposite electrodes (i.e. peaks not along the diagonal) help to demonstrate the phenomenon of crosstalk would represent active stimulation of two antagonistic muscle groups and is unlikely.⁵

rected” electrodes have a smaller area of capture and therefore represent a more local expression of EMG signal, which often results in a lower amplitude but higher frequency signals (Figure 1.8). The electrodes themselves will be discussed in Chapter 2, but one important consideration is obvious upon initial examination. These electrodes typically require a more invasive placement strategy than sEMG electrodes. Even the least invasive of intramuscular methods involve multiple needle punctures to place electrodes within the muscle. Additionally, since the area of capture tends to be much smaller than surface electrodes, signal detection by intramuscular electrodes is much more dependent on electrode placement than surface systems (Figure 1.8). However, intramuscular systems hold the unique benefit of allowing physiologic understanding of muscle actions to inform EMG-based prosthetic control. Addition-

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ally, these systems are incredibly resistant to crosstalk between signals, even when electrodes are placed within adjacent compartments of the same muscle.⁶⁰

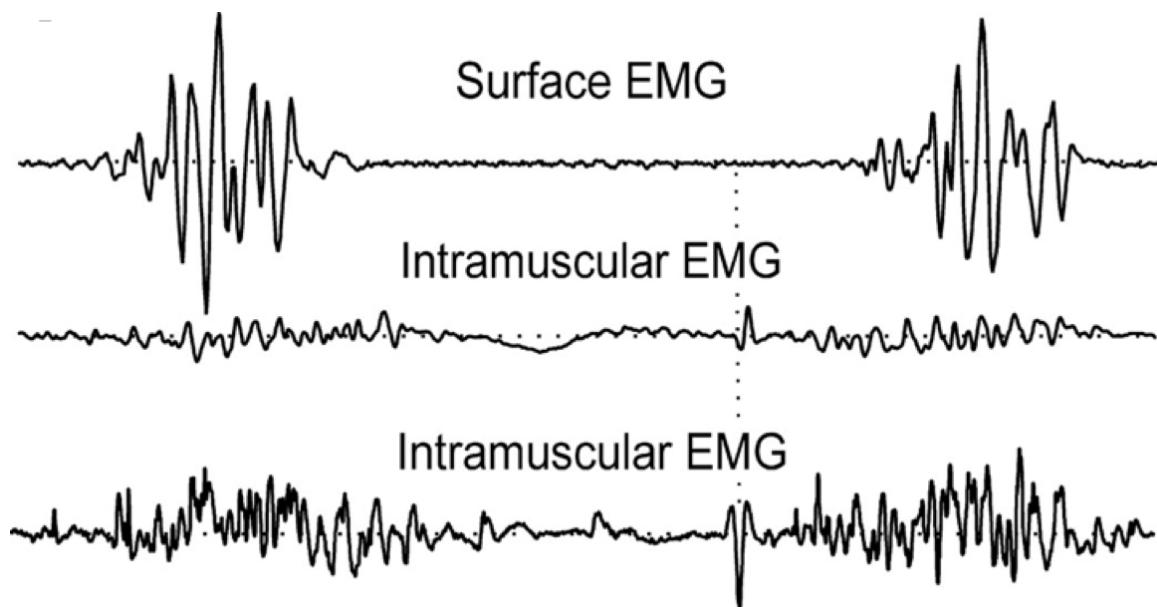


Figure 1.8: Raw EMG signals from the gastrocnemius muscle observed during contraction. Note higher frequency components present in intramuscular signals compared with surface based signals. Additionally, note the difference in two different intramuscular signals depending on their placement within the muscle of interest.⁶

The use of iEMG for prosthetic control allows, and even requires, researchers to prospectively designate muscles of interest to target for electrode insertion. Muscles can be selected based on intended action of the prosthetic; for example, desire to allow for finger grasp with the prosthetic would lead to selecting the *flexor digitorum profundus* as the target for electrode insertion. Following insertion, EMG signal acquired from each electrode can be directly correlated with the muscle group from which it originates, allowing for potentially more accurate decoding of intended movements. The residual anatomy in an amputee’s limb may further help determine placement.

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Indeed, small residual muscle volumes may actually benefit from intramuscular electrode placement since the individual muscle’s electrical activity will be recorded and not lost within stronger signal generated by more intact muscles. Further, muscle groups that are deep, such as the *pronator teres* and *supinator* may benefit from targeted placement.

The primary distinction between the use of surface and intramuscular electrodes for signal acquisition (beyond degree of invasiveness) is the “global” signal capture of the surface methods compared to the more “local” information with intramuscular electrodes. In early comparisons, the benefit of the additional information contained within the global signal compared to the more nuanced information contained in the local signal appeared to outweigh the increased crosstalk seen in surface-based acquisition methods, especially in creating pattern recognition classifiers.⁵ However, as prosthetics become more advanced and natural, highly-dexterous movement is sought, the negative effects of crosstalk with surface signals may come to the forefront and limit the ability of sEMG to control advanced prosthetics. Initial evaluations have demonstrated classification accuracies of only 65-75% when attempting to decode three simultaneous DOFs involving hand and wrist movements.⁶¹

Advances in control algorithms may leverage the benefits of each system and reduce the overall effect of crosstalk on complicated movements. The use of “parallel classifiers” reduces each classifier to controlling a single DOF and then combines the outputs to result in a multi-DOF movement. Exploration of this method has

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started for both surface and intramuscular-based control systems and has yielded some promising results.⁶² An additional way to leverage the benefits of each system may actually be to combine the two mechanisms rather than treat each as mutually exclusive of the other. Intramuscular signals from *pronator teres* and *supinator* have been combined with sEMG signal to control a two DOF prosthetic in offline analysis. The combination resulted in improved path efficiency and classification accuracy (98.96 vs. 95.86%, $p = 0.014$), however with similar completion rates and average speed of movement.⁶³ The role of combining signal or parallel classifiers in controlling multi-DOF in with higher degrees simultaneously online remains unexplored.

1.4 Research Aims

The aim of this research is to allow for dexterous, simultaneous control of a multi-DOF prosthesis. In order to do so, both intramuscular and surface-based control mechanisms will be examined. Ultimately, improved control strategies are only useful insofar as their impact on prosthetic functionality. As such, a component of the research presented within this thesis will focus on the current standards for measuring prosthetic functionality as well as the introduction of novel methods for objective classification of prosthetic functionality. To facilitate a thorough evaluation, the following specific aims have been constructed.

Specific Aim 1: Surface-based EMG for three DOF control using a single and parallel classifiers

Within this aim, the ability to utilize sEMG alone to control three DOFs simultaneously will be explored. These three actions will be wrist flexion/extension, supination/pronation and hand open/close. A single classifier and parallel classifier will be constructed using traditional pattern recognition algorithms for control of a virtual prosthetic limb using both able-bodied subjects and amputees and the results will be compared. These measurements will serve as the basis for comparison with intramuscular systems in future specific aims. Notably, since surface electrode information is collected within a short period after application, this experiment does not address the issues of electrode migration during daily use and the impact of sweat buildup at the electrode site but instead allows for comparisons to “ideal” surface performance.

Specific Aim 2: Intramuscular-based EMG for three DOF control using single and parallel classifiers

This aim will examine the ability to use fine-wire intramuscular electrodes to control a virtual prosthetic in the same three DOFs as *specific aim 1*. Electrodes will be inserted into the muscles representing muscles commonly maintained after

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transradial amputation. This aim will help to demonstrate the effect of local signals for the control of prosthetic limbs, and help to address concerns for robustness between subjects and dependence on electrode placement. Additionally, this will allow for exploration of the use of control strategies that are better suited for intramuscular signals.

Specific Aim 3: Combined sEMG and iEMG control scheme for three DOF prosthetic control

Combined control using both strategies will be attempted in this aim and represents the most significant advancement of this research. A feature-rich parallel classifier with information from each signal source will be constructed using a pre-selected combination of iEMG signals and/or sEMG signals for individual DOFs. Additionally, a single classifier using all available channels of both sEMG and iEMG will be constructed to evaluate performance. This aim intends to demonstrate that the weaknesses of surface systems (electrode migration, electrode interface issues, etc) and intramuscular (local signal only) will be mitigated by combining the two systems.

Specific Aim 4: Evaluation of alternative functional assessment methods for upper extremity prosthetics

This aim will explore the evaluation of upper extremity prosthetic use beyond the typical outcome measure of classification accuracy. Given growing concern that myoelectric prosthetic usage has not expanded despite increased “in-lab” metrics, development of an alternative assessment of functionality afforded by an upper extremity prosthesis represents an important step towards translating improvements in classification accuracy to actual usefulness of the prosthetic limb. Within this aim, we will evaluate a novel tool called the Prosthetic Hand Assessment Measure (PHAM) to track non-traditional outcome measures, such as energy used for compensatory movements and task-completion time for a unique clothespin task, to suggest methods for improving prosthetic functionality.

1.5 Overview of Thesis

Prosthetic control, functionality and acceptance are intimately related. Currently, myoelectric prosthetic research has aimed largely at improving classification accuracy through the implementation of new algorithms based on surface signals. The overarching hypothesis of this research is that the current standard of pattern-recognition,

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surface-based control, warrants reexamination. The addition of muscle-specific intramuscular data may hold the key to expanding the number of simultaneously accessible actions of a prosthetic. Additionally, the overwhelming tide in prosthetics appears to be flowing towards implantable devices. While intramuscular signals seem to be a perfect target for these implantables, findings from this research should help inform which combination of “global” signals and “local” signals provides the highest level of accuracy. Chapter 2 outlines the methods for obtaining intramuscular signals, discussing inherent benefits and drawbacks to each method, ultimately culminating in an explanation of the method chosen for this research. Following this, Chapter 3 will present the crux of the research, the use of surface, intramuscular and combined signals for offline classification of multi-DOF movements. In Chapter 4 the discussion will shift towards assessments of prosthetic usability and functionality and introduce the PHAM methodology and preliminary results. Finally, Chapter 5 will bring together the concepts and results from previous chapters to illustrate the possible future directions for prosthetic control using implantable signals.

Chapter 2

Intramuscular EMG: Methods for Acquisition

2.1 Intramuscular EMG Systems

The use of intramuscular sensors for the recording of EMG signals has been heavily studied in the fields of neurology and physical rehabilitation. In these contexts, the use of intramuscular EMG has advanced the understanding of motor neuron activity in conditions such as myasthenia gravis, syndromes of spasticity and normal physiologic function.^{64–66} Achievements in sensor technology and signal analysis driven by intramuscular EMG use in these fields have set the stage for intramuscular-based control algorithms for upper extremity myoelectric prosthetics. The adaptation of intramuscular EMG to a fully implantable system for control of prosthetic was achieved

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in 2015, when Pasquina et al described the first successful implantation of an array of intramuscular electrodes for permanent use for subsequent prosthetic control capabilities.¹⁴ Despite this milestone, significant work remains to maximize the ability of intramuscular systems to accurately decode intended movements for prosthetic actuation, including improved techniques of signal decomposition and further development of sensor technology. In this chapter, the characteristics of the intramuscular EMG signal, design of current intramuscular electrodes, including fully implantable systems, as well as the future direction for electrode design will be discussed. This discussion will be followed by a rationale for the use of fine-wire intramuscular electrodes for the purposes of subsequent research.

2.2 Intramuscular Signal Characteristics

Like surface-based systems, intramuscular EMG is the summation of electrical signals generated from the muscles within the detection area of the intramuscular electrode. Unlike surface, the small detection size decreases the overall volume the sensor surveys, resulting in a signal more accurately reflecting the local environment of the sensor. The volume of recording is determined largely by sensor design and will be discussed in detail in subsequent sections. Due to the difference in recording areas, there are characteristics of the signal acquired by intramuscular electrodes that vary from surface-based systems. This section will offer a review of the components of

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EMG signals, with a highlight on aspects particular to intramuscular signals. This will improve the understanding of the discussion regarding sensor design in the following sections of this chapter.

2.2.1 Frequency

Intramuscular sensors have been utilized to identify high frequency abnormalities of muscle firing, such as fibrillation.⁶⁷ In this setting, the diagnosis made by detecting firing rate abnormalities with high resolution, and therefore relies on a system able to detect these changes. Due to the effects of large conducting volume, surface-base EMG typically has lowpass frequency cutoff at 400 Hz, which would be below the threshold to reliably detect these abnormalities. Alternatively, intramuscular bandwidth typically extends up to 1 kHz.⁶ For the purposes of prosthetic control, these high frequency components may allow for differentiation between previously indistinguishable signals that can help to drive finer movements within particular grasps.

2.2.2 Amplitude and Amplification

The observed amplitude of an EMG signal represents the summation of current occurring within the volume over which the electrode senses. For surface-based signals, the large volume underlying an electrode allows for overall larger signals. However,

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intramuscular electrodes have an observed volume that is much smaller, often sensing only the local voltage pocket created from current flowing through typically 20 muscle fibers, but sometimes as low as 1-2 muscle fibers.⁷ Signals recorded from intramuscular electrodes have a maximum amplitude of 1-2 mV with placement directly near the nerve input, compared with typical surface recordings of around 10 mV.⁶⁸ One reason intramuscular EMG is able to reliably detect such small amplitude signals is the absence of the high impedance imposed by the skin, which can be as high as $3.5\text{ }M\Omega \cdot \text{cm}^2$.⁶⁹

As with surface-based signals, signal processing relies on analog-to-digital conversion (ADC) of this voltage. Given the resolution of most ADC units (often 2-3 mV), pre-amplification is required to increase the signal gain prior to conversion.⁶⁸ This is often completed with one or more differential amplifiers in series to maximize common-mode rejection ratio (CMRR) and introduce a gain of 10-1000 times. Most researcher involving intramuscular signals preamplify the signal with a gain of 400, which appears adequate to avoid aliasing of the signal while minimizing noise. The small volume over which an intramuscular electrode records also limits the crosstalk when using multiple channels of intramuscular recording (discussed in Chapter 1) from other muscles that may be activated during a certain task (co-contraction). As such, the signal obtained represents muscle-specific signal, rather than the global signal sensed from surface-based electrodes.

2.2.3 Signal Analysis

EMG signal decomposition can be used to examine the firing pattern and characteristics of individual motor units (i.e. a motor neuron and its associated muscle fiber). In particular, decomposition is used to identify individual motor unit action potentials (MUAPs) within the raw EMG signal, and can be attempted from either surface or intramuscular electrodes (Figure 2.1). However, surface-based EMG signals suffer from multiple factors, including cross talk and amplitude cancellation, that limit the reliability and interpretability of motor activity.^{53,70,71} Further, surface-based signals may not be able to accurately decode motor unit activity of muscle fibers that are deep within the forearm due to the larger volume conductor for surface signals.⁷² The use of high-density surface EMG arrays or novel image processing techniques may allow for better determination of underlying motor unit activity from surface-based EMG signals, though this remains an area of ongoing research.^{73,74} Signal decomposition from intramuscular EMG signals has the benefit of having small conductive loss due to a small volume of recording, and relative proximity to the motor neurons without the influence of skin and subcutaneous fat impedance. It should be noted that, unlike surface signals, the recordings from intramuscular electrodes may represent a small portion of the overall motor units activated during contraction and may even miss contractions altogether; therefore, intramuscular signals should be considered highly localized.⁷ One consideration of electrode design involves the detection volume, to allow for capture of a greater number of motor units for analysis.

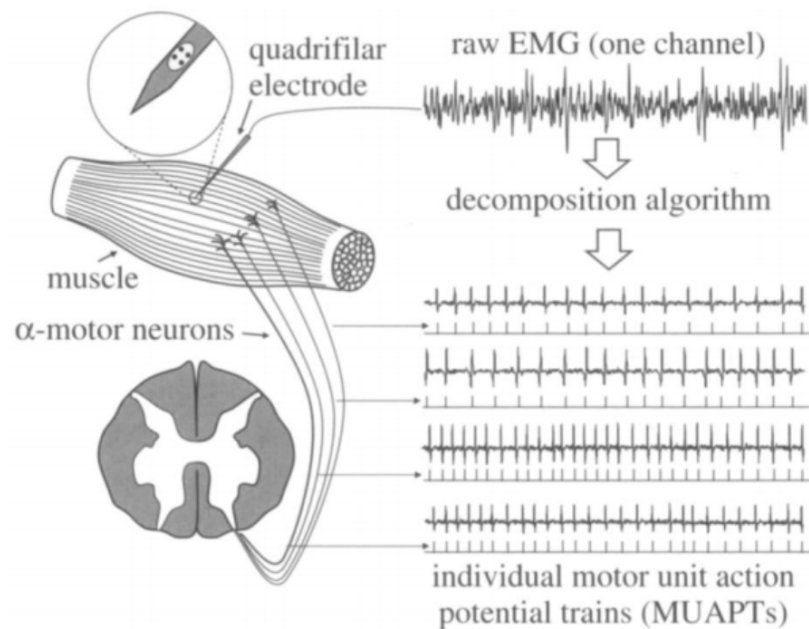


Figure 2.1: Motor unit action potential (MUAP) determination from EMG signal using signal decomposition. The raw EMG is processed to allow for resolving overlapping signals and displaying MUAP trains that occur within the detection volume.⁷

The complexities and computational validity of intramuscular EMG signal decomposition will not be discussed in detail here; however, some elements warrant special attention as they may influence the interpretation of experimental results. Of initial interest is the impact of recording multiple motor units that may be firing in variable patterns. As previously discussed, modifications in electrode detection volume allow for increased “global” EMG information. However, this reduced specificity introduces the variability of the multiple concurrently firing motor units and may increase the difficulty in determining underlying neural drive. Current decomposition algorithms can accurately decode underlying action potentials from up to 12 motor units simultaneously firing (Figure 2.2).⁷⁵ Initial results with newer decomposition methods, such

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as hidden Markov models, have demonstrated decomposition accuracy of up to 95%, yet still require more knowledge of the underlying signal than is readily available in clinical practice.⁷⁶

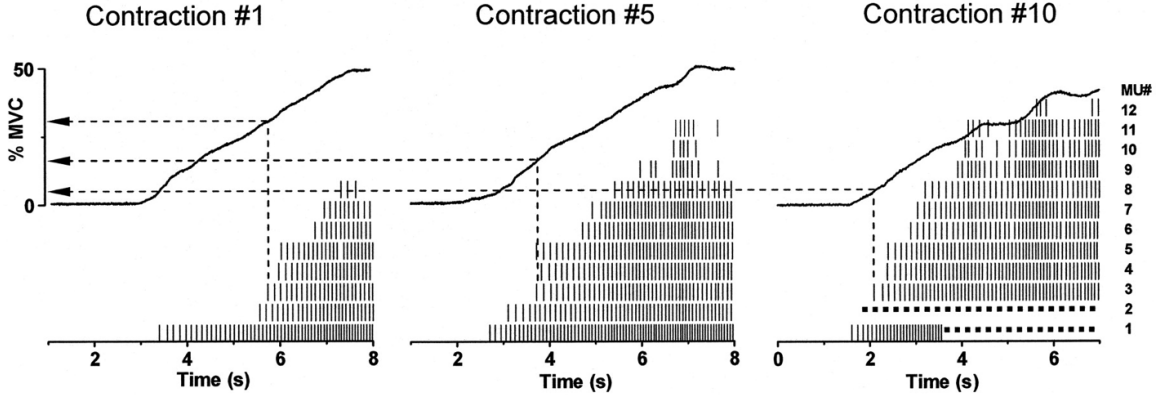


Figure 2.2: Detected motor units within vastus lateralis during progressive contractions performed to exhaustion, with contraction 10 representing the last contraction. Observed is the high variability in motor unit action potentials as well as the maximum motor unit number (12) that can reliably recorded. The the recruitment of additional motoneurons changes from contractions 10, with contraction 10 representing “exhaustion” in which more motoneurons are recruited to perform the same task. This helps to highlight the variability of motor neuron firing patterns, as obtained by intramuscular electrodes, even during repetitions of the same contraction.⁸

It is unclear if this level of signal decomposition is necessary for driving accurate control of prosthetic devices. In particular, pattern recognition algorithms do not require underlying knowledge of the neural input, but do rely on consistent signals. Therefore, factors affecting signal consistency (such as force of contraction) may have a larger impact of decoding intramuscular signals in patients with large residual muscle volume. However, the accuracy of signal decomposition to interpret neural firing even with 1-2 recruited muscle fibers may be helpful in patients with limited retained muscle volume in the muscles of interest within the forearm. This is especially true if

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the retained muscle fibers represent populations that are recruited with different contraction strengths, and therefore have overlapping signals that contain information related to proportional control.

Importantly, motor unit action potentials exhibit variability even within the same motor unit depending on force of contraction and length of the signal acquisition.⁷ High force contractions (greater than 50% of maximum voluntary contraction[MVC]) significantly affect the ability to accurately decompose the intramuscular EMG signal, particularly when the contraction is sustained. In this setting, spike counts decrease during as recording length decreases despite sustained force levels.⁷⁷ Also, the increased force is generated through the recruitment of additional motor units, and firing rates for the initial motor unit may differ with increased recruitment. Further, due to muscle deformation, especially at high force, the motor unit may change its position within the detection volume of the electrode, altering the underlying signal. To this end, more flexible (i.e. fine-wire) electrodes may maintain their position near the motor unit by more readily deforming with the muscle. Orientation of an electrode with respect to the muscle fibers has been shown to affect signal properties, including detectable firing rate.⁷⁸ Experiments involving intramuscular EMG are also designed to encourage force of less than 50% MVC, which may help to reduce some of the variability in both MUAP recruitment and electrode position from experiment to experiment.

2.3 Needle and Fine-wire electrodes

Concentric needles designed for the purposes of detecting muscle EMG signals to determine peripheral nerve injury was first performed by Lord Adrian in British World War I soldiers.⁷⁹ The development and use of this electrodiagnostic technique allowed for elucidation of the function and stimulation patterns of the peripheral and central nervous system, research for which he was awarded the Nobel Prize in Physiology in 1932.⁸⁰ Adrian's original design involved a concentric needle cannula that was embedded with a wire that was exposed at the tip of the needle, creating a detection volume only at the tip of the wire.

Validation of action potential recordings with smaller wires (usually platinum) allowed for placing increased number of electrodes within the cannula.⁸¹ Placement of additional electrode wires within the needle cannula allows for detection of signals from various lengths along the needle, representing an increased spatial distribution as well as potential temporal distribution if signals are recorded as they progress through a motor unit. Multi-electrode concentric needles consisted of combinations of monopolar and bipolar platinum electrode wires within the cannula of a hypodermic needle whose impedance within the range for intramuscular signals was typically around - 12.5 dB per decade.⁸²

The shape of the exposed electrode area determines detection volume, and multiple configurations have been constructed depending on the purpose of recording (Figure 2.3). When configured in a bipolar fashion, these electrodes work through

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sensing a potential difference between the platinum wire and the cannula, which then undergoes amplification with a differential amplifier comparing that signal to a reference typically placed on bony surface on the subject. Despite their continued use in diagnostic purposes for neurology and rehabilitation, concentric needle electrodes have largely given way to fine-wire electrodes for purposes of intramuscular EMG due to the pain associated with a rigid needle within the muscle during movement and increased likelihood of displacement during voluntary movement that would alter the results of action potential sensing.

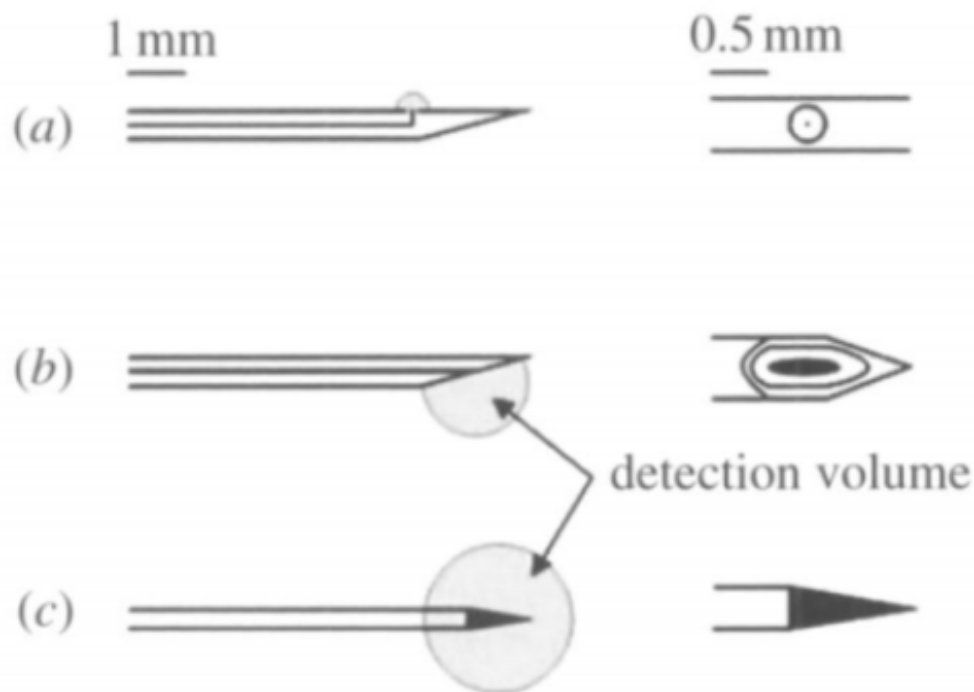


Figure 2.3: Examples of detection volumes as a function of electrode and canula composition. Single core electrodes with side port give the smallest detection volume (a) followed by a slightly more expansive detection volume with concentric core electrodes (b). Finally, monopolar electrodes (c) give the widest area as the tip creates a large circular detection volume.⁷

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Fine-wire electrodes for EMG recording were inadvertently validated in the 1950s, when Lundervolt started removing the outer cannula of single and double core concentric electrodes to determine the impact on signal. Withdrawing the needle to the level of the skin, while leaving the stylet (electrode) in place had no impact on action potential detection.⁸³ Since that time, the technique of inserting platinum or stainless steel fine-wires over a needle and then using these electrodes to evaluate muscle activity has been more thoroughly examined. Like needle electrodes, fine-wire electrodes have a detection volume that is smaller than surface based electrodes, but more accurately quantifies the local muscle fiber and motor unit activation in that area. Fine-wire techniques are particularly useful in recording movements of actively contracting muscles as they have two benefits over concentric needle placement: decreased pain and lower likelihood of electrode dislodgment.⁶⁸ The primary difficulty with fine-wire electrodes is the placement, as most techniques involve placement of electrodes over a needle and are not amenable to repositioning once in place.⁸⁴

Placement of multiple separate electrodes in a regional distribution may reduce the risk of misplacement and allow for more regional information.⁸⁵ Alternatively, recent advances in photolithography and microfabrication have allowed for placement of multiple electrodes within one needle system. In particular, Muceli et al have microfabricated a multi-channel electrode with platinum wire that was spin coated with polyimide and then underwent reactive-ion etching to allow for 16 separate recording sites (Figure 2.4).⁹ The dimensions of this system allow for insertion over

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a 25 gauge hypodermic needle. In validation testing, this electrode has allowed for the signal decomposition of 30 motor units active during a contraction and may offer better insight into neural drive.⁹

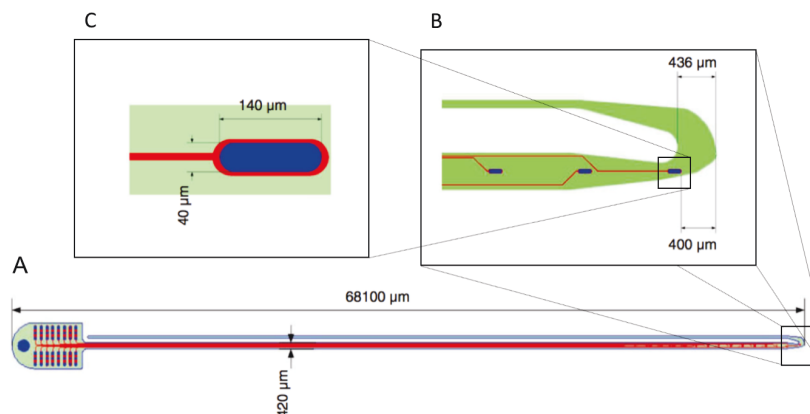


Figure 2.4: Schematic of 16-channel “fine wire” electrode developed by Muceli et al. Wire is platinum based and spin coated with polyimide, then subsequently etched to allow for 16 separate recording sites. The overall length and diameter (A) allow for insertion over a slightly modified 25 gauge hypodermic needle. The electrodes are staggered to allow for differential recording sites (B). Also, the small area of exposed electrode (similar to the previously mentioned single-electrode concentric needle electrodes) allows for a smaller detection volume specific to that exposed site (C).⁹

2.3.1 Impact of Fine-Wire and Needle Electrodes on Signal Quality

One area of increased focus has been the effect of needle and fine wire instrumentation on EMG signal, either through perturbations of the underlying tissue or through alterations that occur in normal movements due to pain associated with placement. When either fine-wire or needle electrodes are inserted, the presence of the foreign

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body within the muscle generates a fair amount of local edema and potential pain. Pain at muscle insertion site has the potential to alter participant movement patterns.⁸⁶ Further, subjects within experiments using intramuscular electrodes report anticipated pain from the insertion and subsequent contraction.⁸⁷ The combination of pain and anxiety can result in a complex alteration of muscle activation pattern, resulting in decreases in rate and force.⁸⁸ If true, this would make the potential of using fine-wire electrodes less appealing, as the information gained regarding local motor unit activity during contractions may be altered and therefore make prosthetic control algorithms less applicable.

Multiple groups have set out to determine the effect of pain caused by electrode placement on the underlying EMG signal and associated movements. Specifically, Smith et al reported low levels of anticipated pain and actual pain when inserting fine wire electrodes into the back of able-bodied participants.⁸⁹ Additionally, these participants did not demonstrate any alterations in the three dimensional motion patterns while performing ambulatory experiments. When comparing correlation coefficients between surface electrodes prior to insertion and after insertion of fine-wire electrodes, there appears to be no difference in the overall activity patterns secondary to insertion of fine-wire electrodes.⁸⁷ Given these findings, it seems reasonable to accept the applicability of intramuscular findings to represent natural motor unit activation patterns. This important distinction allows for progression of the entire experiment.

2.4 Implantable Electrodes

Fully implantable electrodes are the future for creating natural, intuitive interactions with myoelectric prostheses to maximize functionality in amputee patients. Electrodes for the purpose of prosthetic control was first attempted in a transradial amputee in 1980.^{90,91} However, this system required a lead to penetrate the skin to obtain a signal from the implanted electrode, which eventually led to infection and the requirement to remove the module. The recognition of high rates of infection associated with percutaneous leads has fueled the search for fully implantable systems, with the capability of wireless power and data transfer. Further improvements in microfabrication techniques have decreased the size needed for electrode components. The implications of decreased size have become apparent more so in perineural electrodes, which can penetrate and stimulate individual fascicles within a large nerve.^{10,92} Alternatively, EMG-based electrode design improvements involving microfabrication techniques would likely benefit from easier and less invasive insertion techniques rather than smaller area of signal acquisition.

Commercial intramuscular solutions have sought a design that incorporates small, sensitive electrodes, with accurate signal amplification over a large frequency band, encased in an biologically inert substance with low latency wireless data transfer and wireless power. This section will discuss some of the currently available solutions as well as those implantable solutions used for research but on yet commercially available. Review of the components of implantable electrode design will reveal the

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applicability of information gained from fine-wire experiments (current gold standard for research) to develop control algorithms for control of upper extremity prosthetics. Of note, osseointegrated methods, in which the interface is anchored in the bone and then attaches to a prosthetics, are not discussed explicitly, though they have demonstrated promising initial results at one year post-implantation.⁹³

2.4.1 Perineural Systems

Recent advances in perineural electrodes have potential to benefit EMG-based electrode design. The flat interface nerve electrode (FINE) and transverse intrafascicular multichannel electrode (TIME) are two perineural systems that demonstrate many properties consistent with the ideal design for an implantable EMG electrode (Figure 2.5). The FINE electrode has multiple platinum-iridium (PtIR) contacts for either sensing or stimulation.⁹² The contacts and stainless steel leads are housed within a silicone encasing, and the whole system is implanted transverse along the nerve. This configuration has been shown to allow for fascicle-specific stimulation, demonstrating the small detection (and stimulation) areas of each electrode. While these systems are not currently wirelessly powered, the lack of inflammation created by the silicon and the selective stimulation are both characteristics worth emulating in future EMG designs.

TIME-based systems approach selective stimulation by penetrating the nerve transversely and stimulating at different electrode sites along the length of the overall

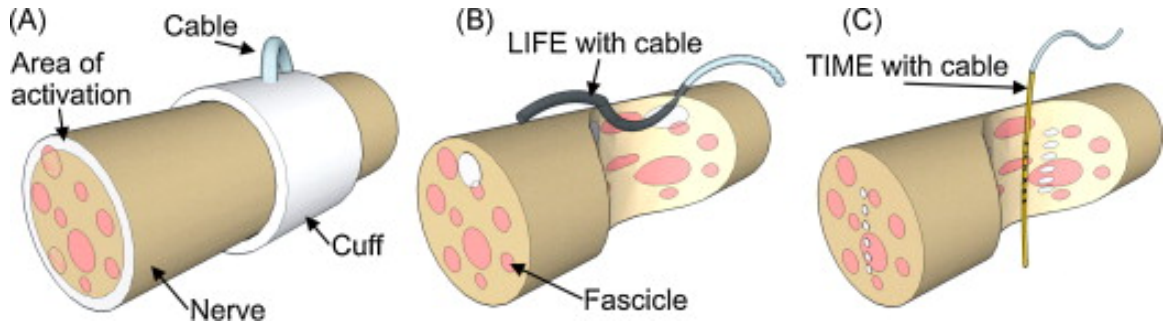


Figure 2.5: Perineural recording and stimulating systems. The standard electrode cuff (A) along with hook electrodes (not pictured) represent the currently used methods. Both LIFE (B) and TIME (C) electrodes are smaller and have the potential to more accurately target individual fascicles. LIFE (B) run parallel to the fascicles whereas TIME (C) run directly perpendicular but directly contact more fibers. The area of activation (demonstrated in white) differs depending on stimulator type.¹⁰

device. Construction involves spin-coating polyimide onto a silicon wafer and then adhering platinum. The TIME device is of particular interest when designing intramuscular systems because it demonstrates the possibility of placing a single device with multiple electrodes across several, potentially independently stimulated muscle fibers with the possibility for accurately decoding signals that arise from a variable cross-sectional location.¹⁰ Experiments with the TIME system have demonstrated increases in the signal-to-noise ratio for recordings as well as lower required stimulation intensity, useful considerations when imagining the ideal configuration for an intramuscular electrode placement.

2.4.2 Bionic Neurons (BIONs)

The current state-of-the-art with implantable electrodes was pioneered at the Alfred Mann Foundation in 2001 with the development of an injectable wireless system

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for neuromuscular sensing and stimulating, termed BIONic Neurons (BIONs).¹¹ Given their small size, the BIONs have been suggested for versatile applications, including functional electric stimulation (FES) in muscle groups for paraplegic limbs and even dysfunctional airway muscles that contribute to obstructive sleep apnea symptoms.^{94,95} However, many characteristics of these implantable capsules make them attractive solutions for control of myoelectric limbs. First, the BION is relatively small and can be injected into the desired muscle group.

The BION capsule is an electrode hermetically sealed within a biocompatible glass chamber, measuring only 16 x 2 mm (Figure 2.6). The electric components consist of a micro-printed circuit board with a custom integrated chip (IC) with an electrode contacts of high quality, biocompatible tantalum and additional platinum-iridium electrode.⁹⁶ There is also on-board read-only memory (ROM) that allows for identification of individual electrodes within an array and therefore targeted communication to specific electrodes. These components all draw very little power, which is provided through inductive coupling with a copper wire and ferrite bar. The coils are self-resonating and amplitude can be adjusted through injection of power into the system (through the use of a capacitor), allowing for two-way communication from the implant to an external coil acting as a sensor.¹¹

Weir et al honed the use of BIONs for myoelectric control with the creation of the Implantable Myoelectric Sensor (IMES) system.¹² The IMES system consists of multichannel EMG information obtained through the use of multiple implanted

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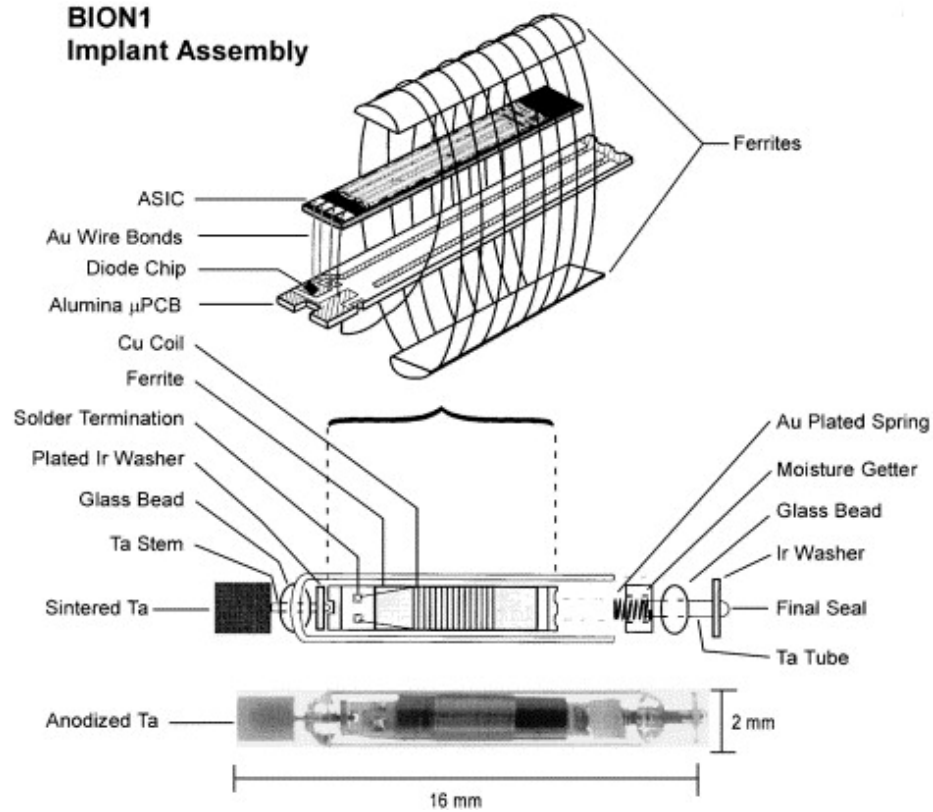


Figure 2.6: An exploded view of the electric and enclosure components of the BION1 implantable capsule. The electric components consist of a custom micro printed integrated chip (IC) and two electrodes capable of receiving wireless power through a self-resonant ferrous and copper coil setup that generates a 2 MHz magnetic field. On board read-only memory (ROM) allows for unique electrode identification with incoming and outgoing signals. Energy is stored on a the tantalum electrode, which provides a biocompatible layer with $5 \mu F$ capacitance. The BION returns information via modulating the amplitude of the oscillating signals from the self-resonant coil with the enclosure.¹¹

BIONs with wireless telemetry data transfer. The overall BION structure is similar to the original design by Loeb et al with the exception of a larger focus on sensing rather than stimulation. In this case, the implantable sensor consists of a precise, low-noise differential amplifier with a $1.0 - 1,000 Hz$ bandpass.¹² Wireless power transfer is once again accomplished with inductive coupling in the setting of an exter-

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nal magnetic field, which the developers suggest may be placed in the socket for the prosthetic. Telemetric data transfer is also accomplished through amplitude modification of the self-resonating coils. In the case of multiple implants, each implant sends the data sequentially, with 32 individual time slots available. If there are less than 32 implanted electrodes, sampling rate can be increased by assigning multiple time slots to a single implant. The IMES system intends to incorporate amplified, band-passed EMG signals repeatedly sampled from multiple muscles to drive the movements of a myoelectric prosthesis (Figure 2.7).¹²

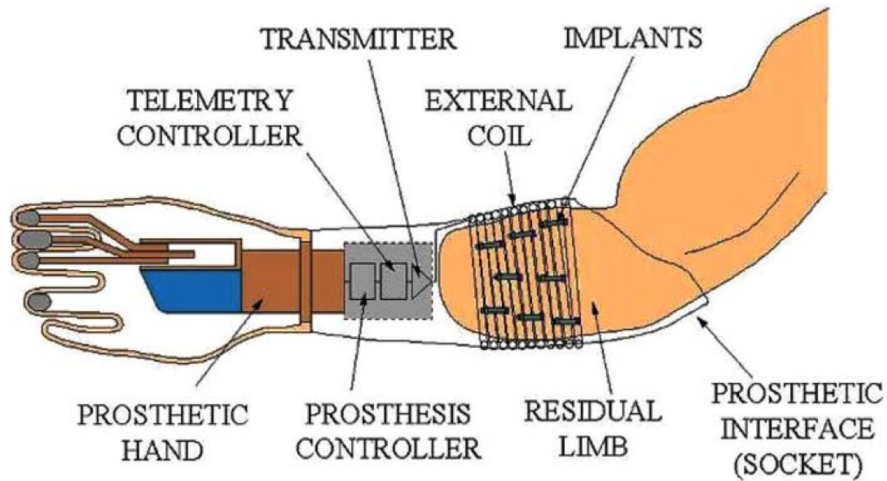


Figure 2.7: Intended design and implementation of IMES systems by Weir et al.¹² The multiple implanted electrodes communicate through wireless telemetry with a receiving coil housed within the prosthesis socket. Signals are decoded through an on-board processor that also drives the movement of an attached advanced prosthetic. The sensors are powered through inductive coupling with a magnetic field also generated by coils within the prosthetic socket.

The use of IMES for control a three DOF advanced prosthetic was demonstrated by Pasquina et al in 2014.¹⁴ In this utilization, eight IMES electrodes were implanted

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in the residuum of a subject's limb. The socket design housed magnetic coils that allowed for inductive charging. An additional electronic box is worn on the user's hip to receive and further process the signals. Of note, electrodes required surgical implantation instead of the injection-based implantation method originally described by Loeb et al. The post-surgical edema resolved within approximately three weeks and the implanted electrodes appear to be well tolerated as of this report. Performance benchmarks are lacking as of yet due to the early stage of development; however, the user does report improved accuracy with prosthetic activation, including when utilizing multiple DOFs and in various positions.¹⁴ Further work is necessary to determine optimal implantation sites/methods, as well as improved socket design and post-acquisition processing, but this implantation represents a significant step forward towards provide natural prosthetic control without the need for daily training or surface mounted electrodes.

2.4.3 Future Development

Advances in electrode design and signal acquisition are two of the major areas for future development. Implantable systems are working on making the movement out of the laboratory and into the commercial realm. Companies such as Ripple Neuro offer miniaturized microprocessors dedicated towards high fidelity multi-channel EMG amplification and analog-to-digital conversion, all housed in a small unit that could be conceivably housed on a prosthetic socket. However, several factors will need to be ad-

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dressed before there is widespread commercial adoption of implantable systems. The available DOFs with widely available prosthetics are limited, and therefore the utility of undergoing a surgery to implant electrodes is in question. Inevitably, prosthetic hands and wrists will become more accessible to the general amputee population, and so the value of implantable systems must be proven in their ability to provide intuitive prosthetic control. The first fully implantable experiments are still in their infancy, and separating issues arising from long term implantation versus issues of decoding and prosthetic control will likely be difficult and ongoing. Additionally, the best design of implanted electrodes is an issue that will become increasingly important as our experience with using these signals for prosthetic movement increases. Results from initial testing with current systems may indeed reveal that an implantable that has the ability to capture more global information, rather than only muscle specific, will be of more use. These questions must be addressed prior to pushing an implantable solution to the entire amputee community.

2.5 Rationale for the use of Fine Wires

The rationale for the experimental design described in the remainder of this thesis is driven by the balance between the advances made with pattern recognition algorithms for surface-based electrodes and the physiologic appeal of intramuscular-based control schemes. Indeed, the entire thrust of this research is to determine the role

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of intramuscular EMG signals (either standalone or in cooperation with surface) in controlling an advanced prosthesis. While fully implantable systems have appeal, they have several limitations which prevent their utilization in this research. First, initial testing with IMES revealed difficulty syncing the input from a second data acquisition source (i.e. a surface based EMG system), which makes it a difficult choice for comparative research attempting to look at both intramuscular and surface-based systems. Second, the best implantable electrode design has not yet been decided. As such, fine wire electrodes offer the greatest benefit of “semi-implantable,” allowing for natural movement of the arm, while also giving high fidelity intramuscular signals. While not the primary intent of this research, the data obtained from working with these fine wire signals has the potential to drive design of implantable sensors, with specifications such as ideal sampling rate, bandwidth and amplification more fully determined. Finally, fine-wire systems do not alter the ability to perform surface recording, and therefore serve perfectly to compare surface and intramuscular systems as well as incorporate information from the two systems together to leverage the advantages of both systems for the development of a truly natural and accurate prosthetic control mechanism.

Chapter 3

Combining Surface and Intramuscular Signals for Prosthetic Control

3.1 Background

To this point, the theoretic benefits of using an intramuscular system make it an attractive alternative to surface-based EMG for control of advanced prosthetic limbs. However, there are significant considerations that must be weighed, and ultimately tested, to confirm the role of intramuscular EMG in prosthetic control. As previously noted, the primary consideration is whether the specificity of local information provides a benefit that outweighs the invasive nature of intramuscular electrode place-

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ment and the loss of more global information provided by surface-based systems.⁵ The goal of this chapter is to provide the experimental setup and results comparing intramuscular and surface-based control patterns for tests of offline classification accuracy with multiple-DoF movements. A justification for the experimental design will become clear from a discussion of current research focusing on the use of intramuscular signals.

Early evaluation by Hargrove et al comparing intramuscular EMG to surface EMG for the control of upper extremity prosthetics demonstrated findings suggesting a minimal role for intramuscular EMG.⁵ In this experiment, able-bodied subjects were equipped with a 16 channel surface electrode array and 6 intramuscular channels. Subjects were asked to perform pronation, supination, wrist flexion, wrist extension, radial deviation, ulnar deviation, key grip, chuck grip, hand open and rest movements. Comparison of average classification accuracies using multiple offline classification methods did not yield significant differences between algorithms with either intramuscular or surface-based EMG recordings (Figure 3.1). The authors therefore concluded that “the benefits of using intramuscular MES [myoelectric signals]...do not outweigh the more global information contained in surface MES for pattern recognition.”⁵ However, as Kamavuako et al have noted, the appeal of a fully implantable system utilizing intramuscular EMG signals makes the finding of similar results to surface-based systems more promising.⁹⁷

With the advent of advanced prosthetics, simultaneous control of multiple DOFs

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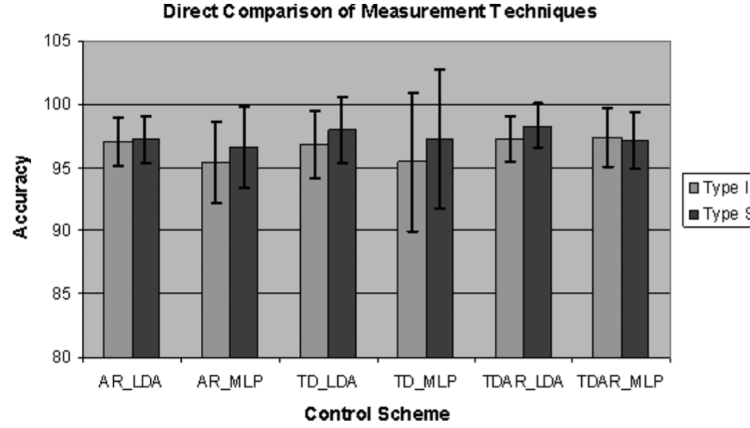


Figure 3.1: Results from Hargrove et al demonstrating classification accuracy comparing surface (Type S) and intramuscular (Type I) EMG-based prosthetic control using different time-domain (TD) algorithms, including auto-regressive (AR/TDAR) linear discriminant analysis (LDA) and multi-layer perceptron (MLP). Classification accuracies represent the average classification accuracies combining all movement classes. There are no statistically significant differences between methods when using the two different input methods for able-bodied subjects using 6 intramuscular channels and 15 surface electrode channels.⁵

has become an increasing area of interest and may serve as a catalyst to reignite the study of intramuscular EMG. Traditionally, classification accuracy for greater than two DOFs has fallen precipitously when using traditional methods, largely due to crosstalk during high DOF movements.⁶¹ Additional methods using surface signals alone have been described, including logistic regression(LR), artificial neural networks(ANN) and nonnegative matrix factorization(NMF).⁹⁸ Classification accuracies for simultaneous movements around the wrist and hand of greater than 90% were obtained in the decoding of two simultaneous DOFs using surface signals only, especially with the use of “parallel” classifiers.⁵⁸ Pattern recognition using linear discriminant analysis (LDA) has also been touted as an effective method for two simultaneous

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DOFs based on Fitt’s Law tests.⁹⁹ However, there is some concern about the ability to extend this methodology beyond two DOFs to control advanced systems.^{98,100} The use of intramuscular signals may help overcome this barrier.

The knowledge of the specific muscles from which a signal is obtained is one of the primary benefits of intramuscular electrode placement. Parallel classifiers, in which there are multiple simultaneously running classifiers that each control a single DOF, appear to take advantage of this physiologic information.⁶² Smith et al performed a Fitts’ law test that tested a user’s ability to utilize multiple, simultaneous DoFs using intramuscular EMG signals to move an on-screen cursor.⁶² This methodology does not allow for determinations of classification accuracy and therefore results relied on alternative measures such as throughput, path efficiency and the time spent activating a given number of simultaneous DOFs. Parallel dual site control appears to allow for movement in two and three DOFs with higher throughput than pattern recognition, but users still tended toward using a single DOF most of the time. Previous reports have already demonstrated increases in these “usability” measures, such as Path Efficiency and Overshoot, when using intramuscular EMG compared with surface EMG for prosthetic control.¹⁰¹ Parallel classifiers, therefore, may help improve classification accuracy in multiple DOFs, but it is unclear if improved accuracy alone will result in increased simultaneous DOF movements.¹⁰² The use of alternative classification strategies, such as LR, appear to enhance the ability to use multiple simultaneous DOFs, but at the cost of classification accuracy for single DOF

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movements.¹⁰³ While encouraging, these reports do not address the “additive” benefit incorporation of intramuscular signals into traditional surface-based classifiers.

Nearly all studies examining multi-DOF have combined the examination of hand-based and wrist-based movements. However, some researchers have explored wrist movement alone, to see if decoding of wrist movements may have fundamental differences from hand movements. While wrist flexion and extension alone are accurately controlled by surface EMG, wrist stiffness (i.e. resistance to flexion or extension) was found to result from concurrent contraction of antagonistic muscle groups in the forearm.¹⁰⁴ Interestingly, this co-contraction dependence is seemingly susceptible to artifact from crosstalk, and may suggest that wrist movements could be more limited in systems with high crosstalk. However, in their original description of targeted muscle reinnervation (TMR), Kuiken et al report a 96.3% completion rate within 5 seconds for wrist movements with surface EMG, even higher than the 86.9% for hand movements, suggesting that users of this novel mechanism are able to rapidly and accurately control wrist movement separate from hand movement.¹⁰⁵

Literature regarding combining intramuscular and surface signals is limited. Initial results comparing able-bodied control of two simultaneous DOFs around the wrist and hand using a combined strategy of intramuscular and surface EMG signals demonstrated improved path efficiency and off-line classification accuracy with the combined system.¹⁰¹ In this setup, the intramuscular data from *Pronator Teres* and *Supinator* were provided by specific intramuscular electrodes. Such a strategy

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leverages the benefit of nearly no crosstalk with intramuscular signals in two muscles highly prone to crosstalk from overlying muscle groups. However, this work has not been extended to advanced DOFs.

For the current study, a unique experimental protocol was developed that allowed for testing of two DOFs around the wrist and one DOF of the hand, either individually (single DOF) or combined (two and three DOF). Hand grasp was limited to hand open and hand close. Specific hand grips were excluded due to the extreme dependence on electrode placement within specific compartments within the extensor and flexor muscles of the hand, as observed by Birdwell et al.⁶⁰ The goal of this study is to explore the efficacy of offline classification of hand grasps and wrist rotation using surface only, intramuscular only or a combined surface-intramuscular control strategies. As such, it provides the first investigation into a combined strategy using intramuscular signals from multiple muscle groups and surface signals from a traditional circumferential array.

3.2 Methods

This study was approved by the Johns Hopkins Hospital Institutional Review Board (IRB 00056264). Intramuscular testing was attempted in one subject on 5 different trials. One of the primary concerns regarding intramuscular placement concerns the high variability with signals due to placement near different motor neuron bun-

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dles with each placement attempt. Utilizing one participant with consistent anatomy allowed for examination of the effects of altered placement positions with each new attempt.

Importantly, several methods were attempted to accurately obtain an intramuscular signal with appropriate resolution and then incorporate that information into simultaneously obtained information from surface EMG signals. A major goal of this work is to serve as a guide for future work within the lab in this area. I will briefly discuss the initial attempts at signal acquisition and highlight their shortcomings. This is intended to allow future researchers to bypass these less suitable solutions or to modify these approaches appropriately to address the shortcomings in a way that may serve their research purposes.

3.2.1 Data Acquisition Methods

3.2.1.1 Overview

All intramuscular signals require a certain amount of pre-amplification prior to being processed by an ADC. Previous reports have cited a gain of between 300 and 400 as adequate for intramuscular signal acquisition.⁵ However, the resolution of the systems used was not reported, as they were typically commercial systems with proprietary hardware. Given the lab's experience with circuit design and the ability to tailor a custom-built solution to the particular needs of this experiment, initial efforts

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focused largely on circuit design. Low signal-to-noise ratio precluded this from being an effective method. Following this initial attempt, a method to get high-resolution, low noise signals was attempted with a combination of a Texas Instruments ADS-1291 amplifier, commonly used for biosignals such as ECG and EEG, and a Nucleo analog-to-digital converter. Despite high resolution, this system did not possess the gain necessary to amplify intramuscular signals. The specifics of each approach, including circuit design, system response and shortfalls, preventing its use are presented here.

3.2.1.2 Custom Circuit Design

Initial investigations began with the design of a custom built circuit. The goals behind creating an in-house amplifier was to allow for a cost effective option with highly specified parameters, including specific amplitude and noise requirements. Further, custom-built design allowed for the implementation of a high-pass filter to remove motion artifact between the two stages of amplification, with the intent of improving overall signal quality. The circuit was designed as a two step differential amplification with an interposed high-pass filter for motion artifact reduction (Figure 3.2). Initial differential amplification is accomplished with an INA-128p (Texas Instruments, Dallas, TX). This amplifier was chosen for its low power requirements (minimum $\pm 2.25V$) and ease-of-use. Further, the INA-128p has input protection up to 40V. The signal output from the initial amplification is filtered with the aforementioned high-pass filter and then directed into the second stage, differential amplification via

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the INA-122 (Texas Instruments, Dallas, TX). This amplifier was chosen since it was a single-supply model and power options coming from the NI-6009 (National Instruments, Austin, TX) were limited to positive signals only. Additionally, it had the same high accuracy, low noise characteristics of the INA-128p. Originally, this amplifier was going to be the single differential amplification step. However, with the idea of expanding to two step amplification, the INA-128p demonstrated many favorable characteristics, including input protection and decreased costs, so the LM7660 (Texas Instruments, Dallas, TX) was added for voltage inversion so that -5V could be supplied and the single supply constraint was no longer needed. The total gain of the system was 410 (2×205), which was consistent with previously reported methods.

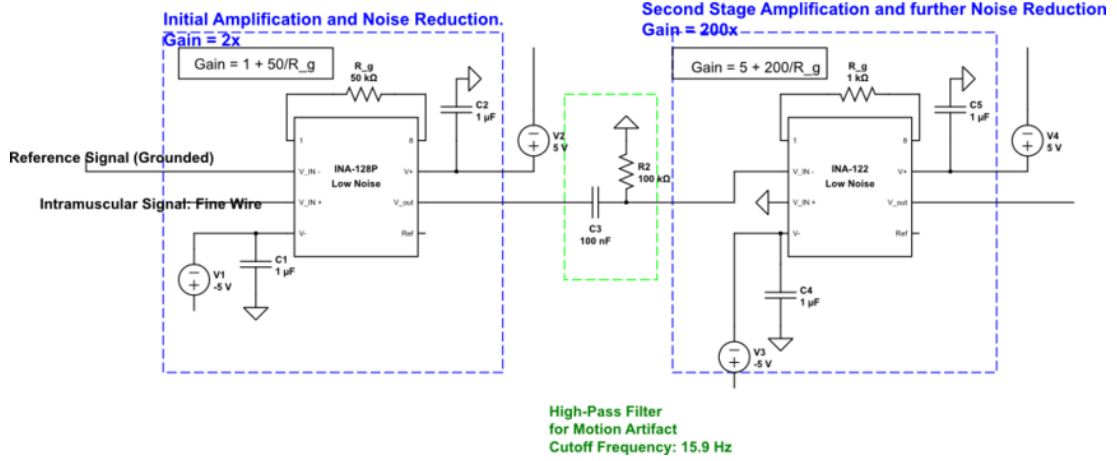


Figure 3.2: Circuit schematic for an individual channel of the custom-built pre-amplification circuit. The input from fine-wire electrodes is first compared to a reference signal through a differential amplifier with the INA-128p. As seen in the schematic, amplification is determined through resistor selection bridging pins 1-8. In this case, amplification over the first part is 2x. The circuit then incorporates a high-pass filter to remove motion artifact, with a cutoff frequency of 15.9 Hz. The second stage amplification occurs using a INA-122, which provides a gain of 205 and an additional step of noise reduction through differential amplification. The output from this circuit connects to the NI-6009 DAQ for processing.

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Initial testing was performed using the differential inputs from the two fine-wire electrode poles. However, this testing did not reveal any appreciable signals; therefore, differential input was performed between a reference signal placed on the elbow and the input from the bipolar intramuscular electrode. In this setup, signal from the reference was also grounded on the circuit, as is typical with many of the amplifier circuits studied. This allowed for some signal detection but very unfavorable signal-to-noise ratio (SNR) still. Despite better shielding, the problem with poor SNR could not be rectified. Therefore, this method was abandoned.

3.2.1.3 ADS-1291 and Nucleo F411RE

The next method attempted for intramuscular signal acquisition was through the use of ADS-1291 (Texas Instruments, Dallas, TX). Each ADS-1291 is a single channel amplifier with high resolution (24-bit). The benefit of this proposed system was the high accuracy, the built-in digital conversion and the recent support for the device in recording EMG biosignals.¹⁰⁶ It was proposed that the low gain could be offset by a high resolution (Equation 3.1) signal that would allow for pattern recognition-based algorithms to have more information with which to work. Indeed, initial analysis appeared to demonstrate spiking potentials commonly seen from action potentials in spiking muscles or neurons (Figure 3.3). Following amplification and conversion, signals were sampled using the Nucleo F411RE (STMicroelectronics, Geneva, Switzerland) at 1024Hz. Surface signals were amplified using 13E200 (Ottobock, Plymouth,

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MN) amplifiers and sampled at 1024Hz using the NI-6009 (National Instruments, Austin, TX).

$$2^{24} = 16777216$$
$$\frac{10 \text{ VDC}}{16777216 \text{ bits}} = 0.59 \mu\text{V} \quad (3.1)$$

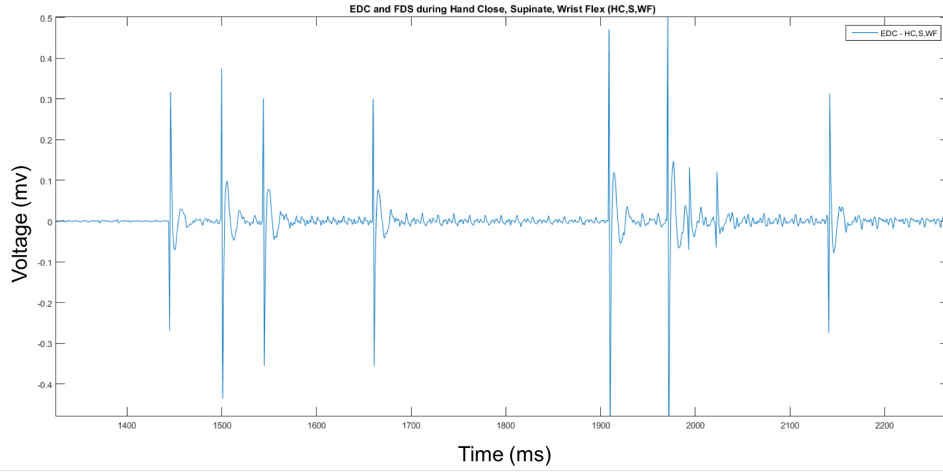


Figure 3.3: Example output from ADS-1291 and Nucleo F411RE intramuscular recording setup. The spikes appear similar to what would be expected from spiking potentials in active muscles or nerves. However, the first hint at possible error is the fact that the spiking frequency is so slower than would be expected.

Using this setup, four sets of combined intramuscular and surface experiments were performed. Signals were then filtered and used to construct a three DOF classifier in which classes included all one, two and three DOF classes for a total of 27 classes. Classification using only surface based signals yielded an accuracy of 63.7%, which is consistent the previous literature attempting to do similar classification. However, classification with intramuscular alone was very poor (approximately 4%) and ap-

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peared similar to the expected outcome due to chance. Interesting, combining the two modalities actually *decreased* overall classification accuracy to 62.51%. In order to determine the cause of this effect, the MAV pattern for intramuscular signals was explored. In this evaluation, the MAV was approximated as a normal distribution, which the mean and standard deviation derived from intramuscular data obtained from a single muscle during a single movement.

The first evaluation examined the MAV of the FDP during a hand open and hand close movement. In this analysis, the FDP should be heavily activated (higher MAV) during hand close movements, and relatively quiescent during hand open maneuvers. However, visual inspection of the distributions reveals that they are very similar (Figure 3.4). Statistical analysis demonstrated a very high likelihood that these distributions were identical ($p \gg 0.05$). To confirm, a similar analysis was conducted for supinator activation during supination and pronation (Figure 3.4). Despite a seemingly higher degree of separability, the signals were also statistically indistinguishable ($p \gg 0.05$). A brief preliminary trial was performed in which the participant performed 5 trials of grasps in one, two and three DOFs. In that trial, the classification accuracy was 4.5%, which is slightly greater than chance (3.7% or $\frac{1}{27}$). Given this finding, this method was deemed not sensitive enough to detect intramuscular signals from background noise and therefore was not used.

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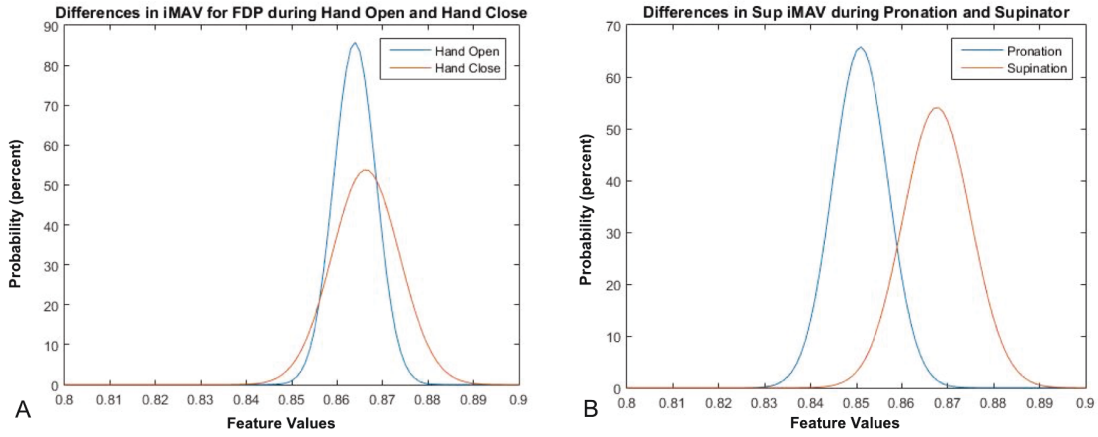


Figure 3.4: Both PDFs demonstrate high degrees of overlap for signal intramuscular MAV (iMAV) feature intensity during antagonistic actions. For FDP, MAV would be expected to be much higher during Hand Close maneuvers. Likewise, for Supinator there would be an expected higher iMAV during Supination. Abbreviations: *Sup*, Supinator, *iMAV*, intramuscular MAV.

3.2.2 Motion Labs Y-03 Preamplifiers

Due to the failure of the previous designs, the decision was made to use a commercial solution. The Y-03 preamplifier (Motion Labs Systems Baton Rouge, LA) is an active preamplifier with a gain of 300. The preamplifier has internal protection against radio frequency interference, which was originally a concern given the long wire length of the fine wire electrodes and the concern that they may act as an antenna. The unit has a low-impedance output to reduce the effect of cable noise and cable motion artifact from the unit itself. The hardware is capable of providing 300 times gain at 1 kHz with a common mode rejection ratio (CMRR) greater than 300 at 65 Hz. The preamplifier has a wide bandpass from 15 Hz to 2,000 Hz.¹⁰⁷ These characteristics make it an ideal preamplifier for intramuscular signal detection. An initial

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collection of the data obtained from this system demonstrated accurate detection of signals within the expected frequency band and of the expected voltage (Figure 3.5).

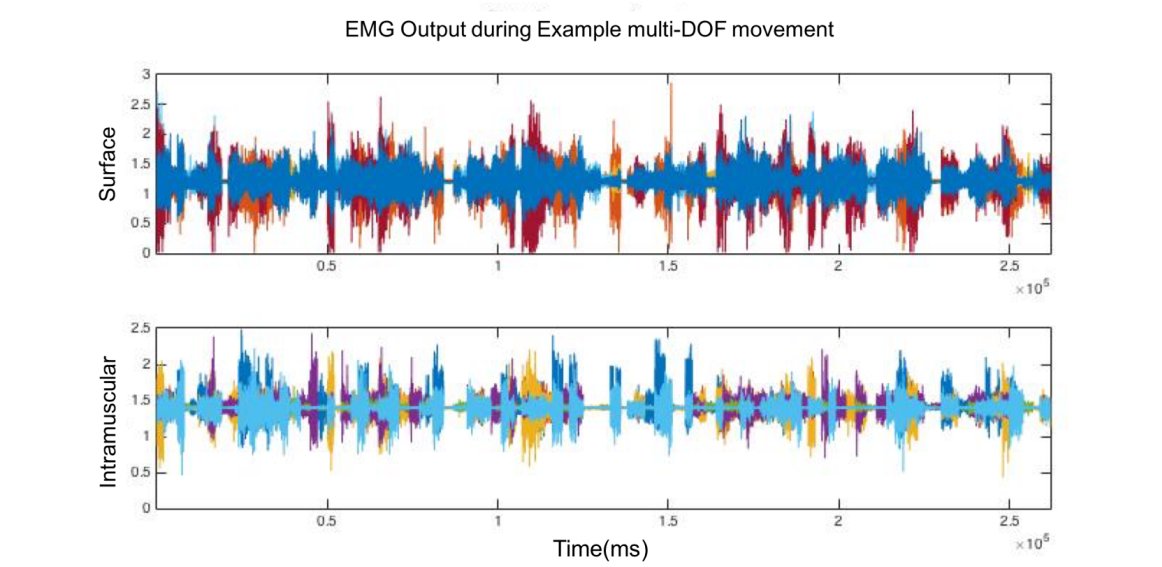


Figure 3.5: Example of surface and intramuscular EMG outputs using the Y03 preamplifier system for intramuscular signals for a 27 movement experiment. Time on x axis is in ms and extends the entire length of the experiment. Color changes in each recording represent individual electrodes, 3 for each signal acquisition type. There is excellent frequency response. Signal amplification for Y03 amplifiers is 300, which accounts for the similar amplitudes of the output from the surface and intramuscular systems. Of note, there are much sharper distinctions for intramuscular due to low crosstalk.

3.2.3 Muscle Targets for Intramuscular Electrodes

Muscle selection for intramuscular electrode placement warrants specific consideration as untargeted placement has been shown to not result in classification accuracy improvements.⁹⁷ Since the goal of this research is to examine multi-DOF movements, muscles that control each individual DOF should be prioritized, with subsequent con-

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sideration given to the difficulty of electrode placement. We selected for targeting were the *Flexor Digitorum Profundus* (FDP) and *Extensor Digitorum Comminis*(EDC) for hand closing and opening, respectively. The FDP was chosen as opposed to the *Flexor Digitorum Superficialis*(FDS) in part because at each cross-sectional position, the FDP has a greater area for potential electrode placement than FDS, thus increasing the chance of successful targeting. The *Abductor Pollicis Longus*(APL) was selected for hand opening. Given that it is commonly co-contracted with the EDC during hand opening but not wrist extension, it was hypothesized that inclusion of the APL would be useful in helping to distinguish these two movements from each other, which both involve EDC activation. Future targets to help determine this movement could include *Extensor Carpi Radialis* and *Extensor Carpi Ulnaris*, though testing of these muscles was not performed in this study.

The *Pronator Teres*(PT) and *Supinator*(Sup) were chosen for their control of wrist rotation. It was hypothesized that the deep position of the PT may contribute to some of the crosstalk commonly experienced during pronation and supination, especially when hand grasps are currently attempted. Indeed, as discussed in Chapter 1, the course of the pronator lies “between” the EDC and the FDP and FDS, making it an understandable source of crosstalk.

Muscles chosen for targeted placement in this study were reviewed with a certified Physical Medicine and Rehabilitation physician and deemed likely to be present after a mid-shaft transradial amputation. As such, they help to represent targets that may

be more accurately translatable from the intact user to an amputee population.

3.2.4 Data Acquisition

Eight sEMG signals and six iEMG signals were continuously measured from a single upper extremity. Intramuscular signals were obtained from six differential fine-wire electrodes (hooked wire electrodes: two 40-gauge Teflon-coated steel wires in a 27-gauge 12.5 mm hypodermic needles). Electrodes were placed within the FDP, EDC, Sup, PT, APL and FCR. During one placement procedure, the *Flexor Carpi Ulnaris*(FCU) was probed instead of the FCR. This occurred because the FCU is more lateral (with reference to arm's center-point) than the FCR and easier to select since it has less proximity to the FDS. Additionally, there were no overlying surface electrodes over the FCU and its signal was likely not highly captured by surface-based electrodes. Previous work has demonstrated a significant reduction in signal intensity with lateral displacement of the muscle in regards to the surface electrode of more than 10 degrees.¹⁰⁸ Like the FCR, the FCU controls pure wrist flexion without any finger flexion.

The insertion procedure was conducted in the presence of a board-certified physical medicine and rehabilitation physician with extensive experience in EMG-based nerve conduction studies who helped to verify correct placement. Insertion technique was initiated with anatomic determination of optimal placement sites through a combination of anatomic landmarks and provocative maneuvers. Following identification,

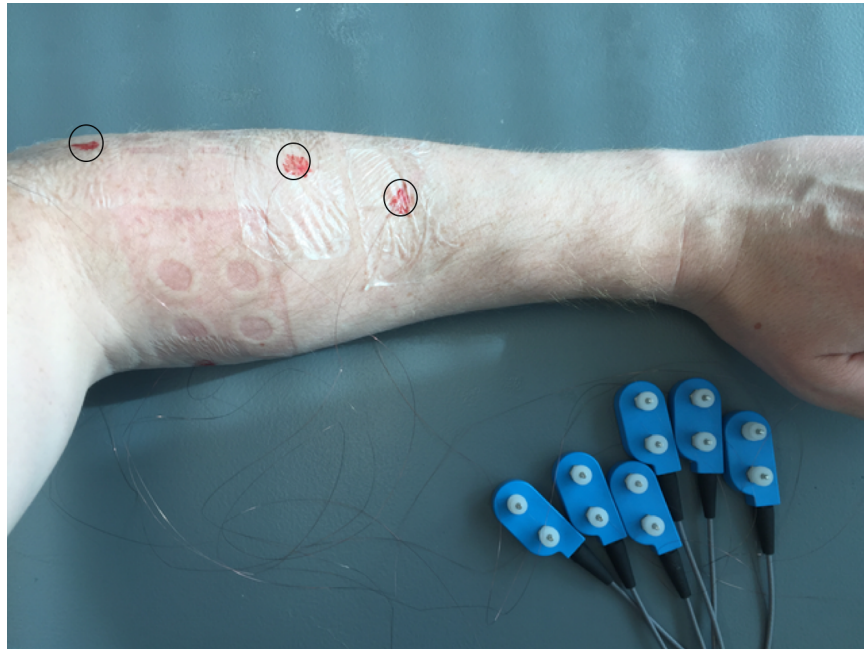


Figure 3.6: Fine wire electrode insertion. Sites are marked with black circles. Following intramuscular fine wire insertion, electrodes are taped down to the skin with adhesive and subsequently attached to the Y03 preamplifiers (pictured in blue).

5% lidocaine cream was applied to the skin overlying the target area. Lidocaine cream was allowed to dwell 10 minutes before the start of the insertion technique. Insertion was first conducted with a 28-gauge microstimulator needle. Twitch stimulation was initiated with the LifeTech Model-IV Micro-Stimulator (Life-Tech Inc, Stafford, TX) and power was increased until muscle contraction was identified. For areas with multiple overlying muscles, correct muscle placement was confirmed through identification of contraction pattern consistent with the target muscle. After confirmation of target muscle placement, the microstimulator needle was removed and the fine-wire electrode was inserted to the identical depth and trajectory of the microstimulator needle (Figure 3.6). Electrodes were secured in place following insertion. For surface

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EMG, signals were recorded using paired differential electrodes placed equidistant around the forearm at the area of greatest muscle mass. Care was taken to avoid contact between fine-wire electrodes and surface electrodes. Following insertion, the signal was tested to verify appropriate recording (Figure 3.7).

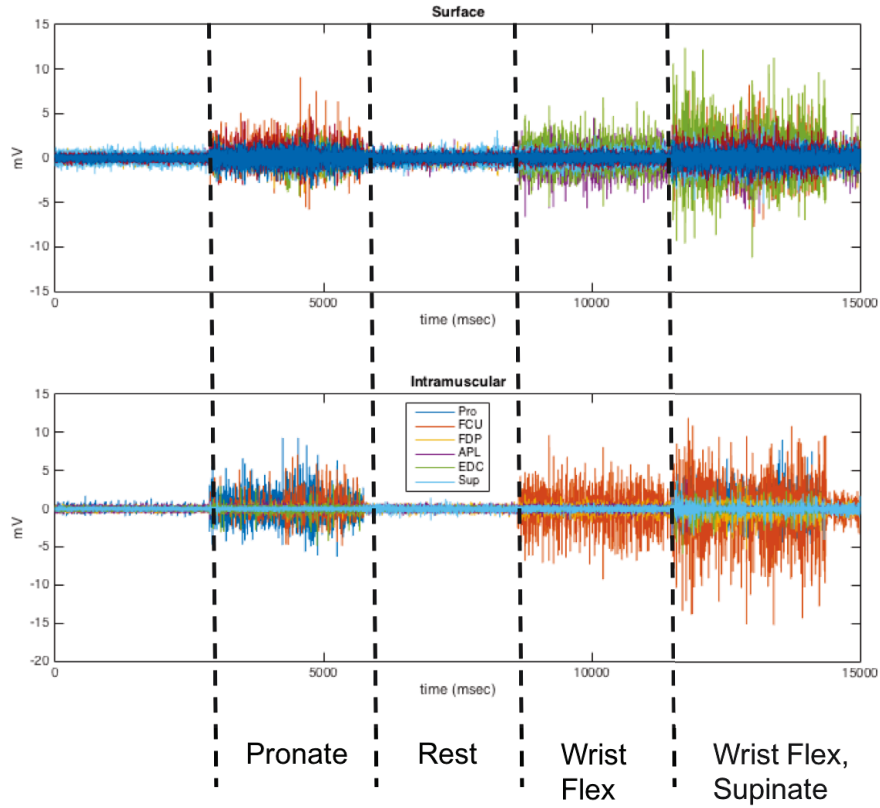


Figure 3.7: Representative waveforms following insertion. The different colors for each recording (surface and intramuscular) represent different electrodes. In the case of intramuscular, muscle names corresponding to each electrodes are provided. As can be seen, there is good amplification and frequency response with both sets of electrodes. The intended movement is recorded below the figure. Intramuscular signals are high amplitude if the involved muscle is activated during the movement, as expected. Additionally, the superficial electrodes tend to demonstrate a broader array of activation.

All signals then underwent filtering with a 20-500 Hz digital bandpass filter and 60

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Hz digital notch filter using Matlab 2014B (Mathworks, Inc., Natick, MA). All signals were z-scored across all trials prior to analysis. Features in the time-domain (TD) were extracted from a 200 ms moving window with 175 ms overlap. Time domain features of interest were mean absolute value, waveform length, signal variance, slope-sign change and zero-crossings.¹⁰⁹ This resulted in 40 surface features and 30 intramuscular features for each trial.

3.2.5 Experimental Protocol

The protocol was devised to test all three DOFs as combinations of one, two and three DOF movements (Figure 3.8). This combination of movements was performed for three reasons. The first is to determine the impact of the incremental increase in the DoF on the classification accuracy under a surface-based control scheme. The second was to allow for eventual incorporation of intramuscular data into a combined control strategy. Finally, by having the DOFs capture in different combinations, this allows for the construction of multiple “parallel” classifiers, which has been proposed as a method to increase the accuracy and throughput of control strategies for advanced prosthetics with high DoFs.

The participant initiated the experiment with the forearm and hand in anatomically neutral position. The participant was then prompted to perform movements through an on-screen GUI that both demonstrated the movement and provided written instructions (Figure 3.10). Each subject was given four seconds to obtain the

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position and maintain a steady contraction strength, after which recording of EMG signals took place for three seconds. A trial consisted of a random-ordered presentation of all 27 movements previously outlined. To assist in subsequent classifier construction, data from 5-6 trials at a time were deemed a training/testing session and used for offline analysis together.

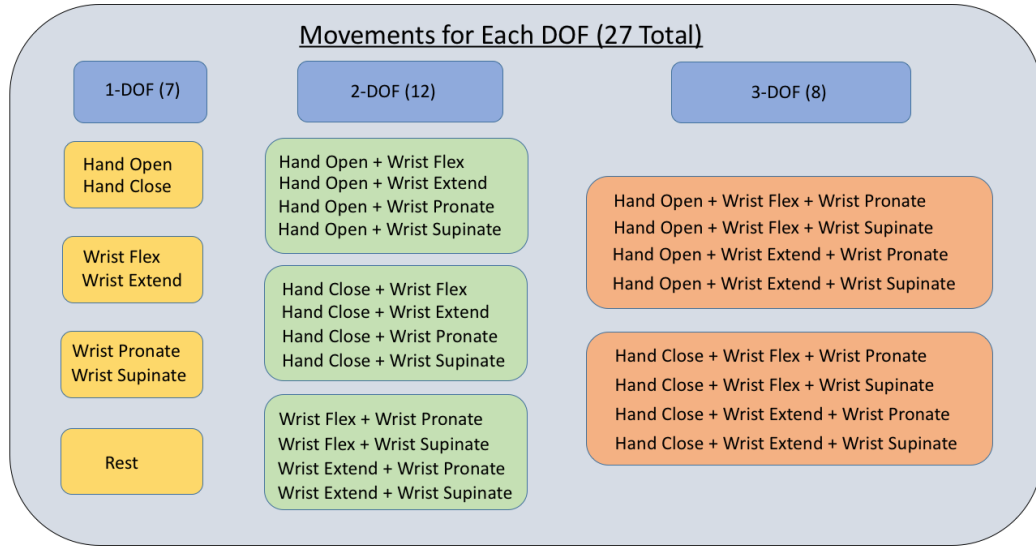


Figure 3.8: Outline of all movements performed during training period, for a total of 27 movements. Movements ranged from single DoF movements to three DOF movements, with all possible combinations of each movement. All movements listed are performed during a single training period. Performing movements of multiple, differing DoFs allows for construction of unique classifier combinations, which may allow for control of a particular DoF with the EMG source (intramuscular or surface) that has demonstrated the best performance for that movement.

Two contraction strengths were tested: strong ($> 70\%$ MVC) and moderate (30-40% MVC). The subject was asked to maintain the same contraction strength during the course of a trial group (5-6 groups of 27 movements) to allow for classifier construction. The hypothesis for this aspect of the methodology was that increased muscle

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contraction strengths would recruit additional motor units and therefore decrease the impact of placement. As such, the two trial groups with strong contraction strengths were tested on separate days to see if their classification accuracy was maintained from day to day. In order to reduce the effect of fatigue, the participant was allowed to rest after each 27 grasp trial. The subject was asked to complete a minimum of 5 trials, with an additional 6 being completed if tolerated. Of note, all experiments were completed with the subject's elbow flexed 90° and forearm and hand in neutral position. This allowed for standardization of wrist flexion/extension and rotation prompts (Figure 3.9).

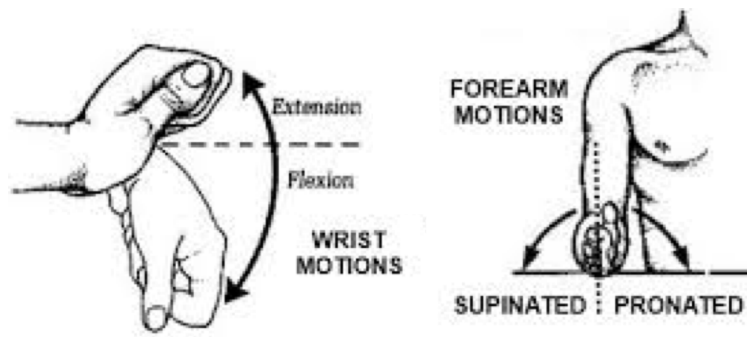


Figure 3.9: Wrist movements tested in this experiment. Wrist flexion/extension and rotation are performed with reference to anatomic neutral positions, as demonstrated in the cartoon.

3.2.6 Classifier Construction

Following testing, classification was completed using linear discriminant analysis (LDA) classification within Matlab®. Initial testing was conducted with a single classifier that accounted for all DOFs (27 grasp and wrist movement patterns). The



Figure 3.10: Examples of one, two and three DOF movement prompts during the experiment. The display was made to provide the written instructions and a visual prompt of the movement.

classifier was constructed using data from the following datasets: surface signals only, intramuscular signals only, surface and intramuscular signals from all channels and, finally, surface signals and intramuscular signals from *pronator* and *supinator* only. Pronation and supination are thought to have significant impacts on the crosstalk of surface-based signals.^{110,111} With this work, the hypothesis was that additional information from the state of the wrist rotation could be used to drive a better classifier by counteracting some of the effects of the signal crosstalk.

An additional classifier method was tested using parallel classification with pattern recognition. These methods were modified from previously described dual-site parallel classification methods in which EMG recordings during a single DOF using intramuscular signals from antagonistic muscle pairs was used to create a multi-DOF classifier.^{62,103} However, in the method presented here, parallel classifiers were created using a combination of surface signals and intramuscular signals, without limitation to particular muscle groups. In order to construct this classifier, each DOF could be in one of three states: Action 1, Action 2 or Rest. For instance, with the hand grasp

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DOF, the three states are: Hand Open, Hand Close and Rest. A pattern recognition classifier was then constructed for each DOF individually using all 27 movements. This led to the formation of three LDA classifiers, the output from which was combined to determine the accuracy of a fully parallel classification strategy.

Classifier accuracy was determined by withholding 1 of the trials for testing and training on the remaining 5 or 6 trials. In order to account for the inter-trial variability, the testing trial was alternated between all available trials. Accuracy results were subsequently averaged.

3.3 Results

The subject was able to tolerate the insertion procedure. Also, it was found that intramuscular electrodes remaining in place for more than an hour caused significant soreness. However, there were no bleeding complications and no observable instances of inadvertent nerve stimulation (as manifested by stimulation of multiple muscle groups with low stimulation voltage).

3.3.1 Single Classifier

For all tested methods (independent surface and intramuscular or combined surface and intramuscular), moderate contraction strength yielded higher classification accuracies compared with strong contraction (Table 3.1). For the remainder of testing,

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trials completed with moderate contraction strength were used. There was no significant difference in the results obtained from initial testing using moderate contraction strength and the “late” test using moderate contraction strength (iEMG: 70.9% vs 71.37%, $p = 0.913$, sEMG+iEMG: 87.63% vs 84.845%, $p = 0.333$). Early and late moderate contractions are both referred to as “moderate” contraction strength hereafter.

	Strong Contractions % (SD)	Moderate Contractions % (SD)	p-value
sEMG	68.17 (± 5.64)	75.91 (± 6.63)	0.002
iEMG	57.96 (± 12.54)	71.14 (± 7.28)	0.005
sEMG + iEMG	72.00 (± 12.29)	86.79 (± 4.55)	0.002

Table 3.1: Averaged Classifier Accuracy with Strong and Moderate Contraction Strength

Surface-based classification outperformed intramuscular alone classification for all contraction strengths (Table A.1). Classification accuracy differences between sEMG and iEMG were greater in the strong contraction group compared to moderate contraction group (10.21% vs. 4.77%), but overall performance was better in the moderate contraction group. Two combined classifiers were constructed, one incorporating all intramuscular data and one incorporating data only from the pronator and supinator intramuscular electrodes. Both classifiers constructed from combined intramuscular and surface data resulted in improved classification accuracy when training was performed using moderate contractions but not with strong contraction train-

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ing/testing. Training with moderate strength contractions and then constructing a classifier with the data from both surface and intramuscular resulted in the highest classification accuracy for the single classifier (86.79%).

With offline LDA classification analysis, the repetitions that are chosen for training and testing can impact the reported accuracy of the classifier. Variability in the classification accuracy between different training and testing groups was measured by calculating the standard deviation of the classification accuracies. Standard deviation was highest among the strong contraction groups (Table 3.1). In the strong contraction group, classifiers constructed with intramuscular signals (either alone or in combination) resulted in the highest standard deviation. A full list of the accuracies with each training and testing combination is listed in the Appendix. Interestingly, classification accuracies in the moderate group ranged from 80.17% up to 94.12%. For the remainder of this report, the accuracies will be reported as their averaged value among all combinations for a certain signal type.

	Strong Contractions %	p-value	Moderate Contractions %	p-value
sEMG	68.17	-	75.91	-
iEMG	57.96	0.007	71.14	0.003
sEMG + iEMG (all channels)	72.00	0.160	86.79	< 0.001
sEMG + iEMG (PT/Sup only)	68.75	0.773	78.42	0.253

Table 3.2: Classification Accuracy for Single Classifier for all simultaneous DOFs. constructed with sEMG, iEMG and combination strategies. P-values are calculated in comparisons with sEMG of the same contraction strength.

Not all classes resulted in identical impacts on classification accuracy. Namely,

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the addition of some classes resulted in larger changes in accuracies than others, with these impacts being different among sEMG and combined strategies (Figure 3.11). Figure 3.11 was examined to determine which individual classes resulted in the biggest reduction in classification accuracy. Movement class 15 (Hand Open, Wrist Flex and Wrist Supinate) and 18 (Hand Open, Wrist Extend, Wrist Supinate) resulted in the most significant drop in classification accuracy when included. When these two states were excluded, all classification accuracies increased (Single Classifier, sEMG: 78.52% (± 5.88), iEMG: 74.06% (± 6.79), sEMG+iEMG: 88.37% (± 5.06)).

As suggested given the overall better classification accuracy with combined systems, the combined system appears more robust to incremental additions of movement classes. The incremental addition of all classes with one, two or three DOFs was examined by grouping all movements into those requiring one, two or three DOF movements. Classification accuracy was the highest for combined strategy at all DOFs (1 DOF: 96.75%, 1+2 DOF: 90.47%, 1+2+3 DOF: 86.23%). Surface EMG demonstrated the most significant reduction in classification accuracy with the incorporation of two DOFs (94.08% vs 80.83%, 1DOF vs 1+2DOF) (Figure 3.12).

3.3.2 Parallel Classifier

Parallel classification was performed for moderate contraction strength training as this was the benchmark for comparison based on performance in the single DOF group. Overall, parallel classifier performance resulted in lower classification accuracy

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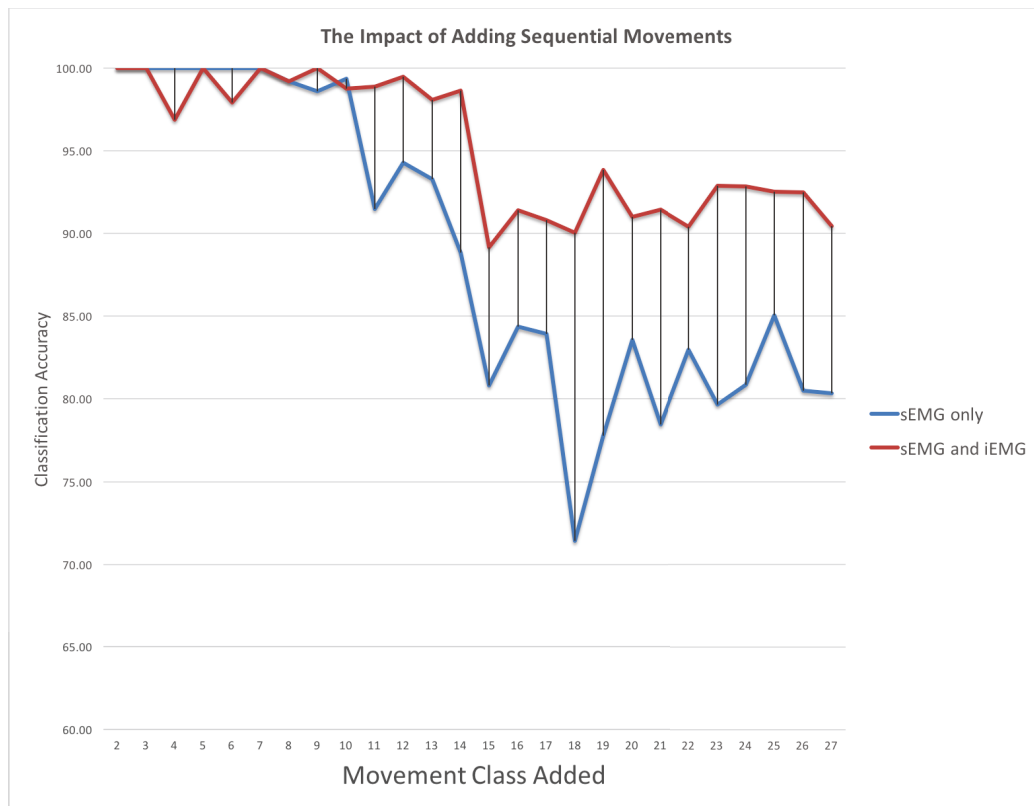


Figure 3.11: The differential impact of adding sequential movements. Classification accuracy decreases with additional movements. However, the impact of an individual movement on incremental changes in classification can be seen by the decrease or increase in overall accuracy imposed by adding that class. Of note, most of the largest decreases come from the addition of three DOF movements, such as class 18 (Hand Open, Wrist Extend, Wrist Supinate).

for each classification strategy (Table 3.3). Within the parallel classification group, sEMG and iEMG performed similarly (66.84 vs. 63.68%, $p = 0.11$) and were both outperformed by a combined strategy using all intramuscular EMG channels (81.04 vs 66.85 or 63.38% $p < 0.001$). Combined strategy using all channels also outperformed the more limited combined strategy with intramuscular signals from pronator and supinator only (81.04 vs 70.61%, $p < 0.001$). Inclusion of any intramuscular data resulted in improvement over individual strategies of sEMG and iEMG-based clas-

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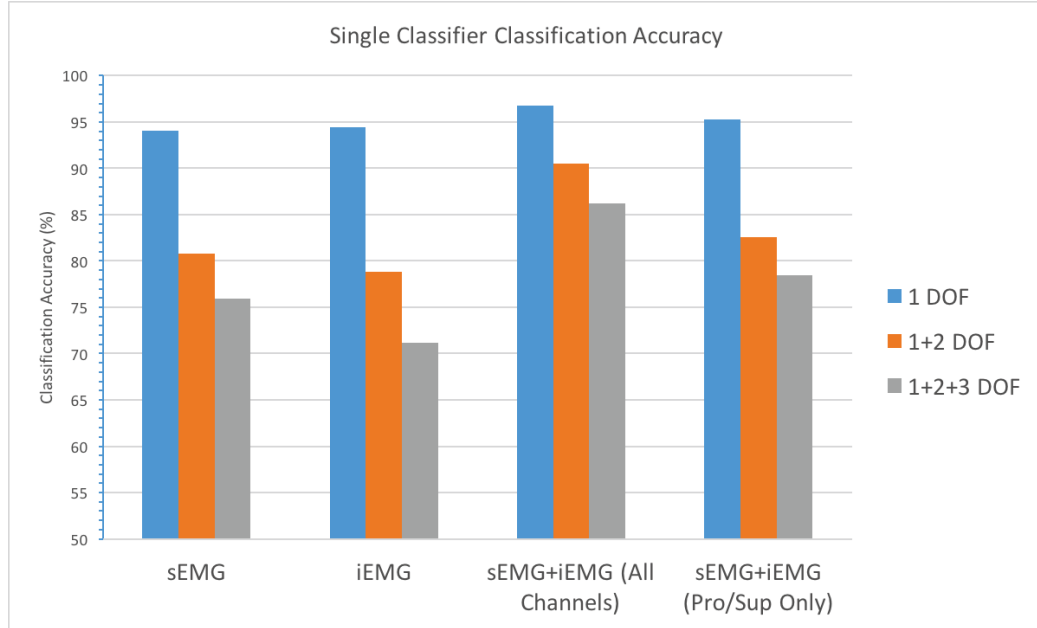


Figure 3.12: Examination of impact on incremental addition of DOFs on classification accuracy for a surface classifier. With the increasing number of DOFs, there is a reduction in the classification accuracy for every classifier. Combined surface and intramuscular appears to be the most robust with additional DOFs.

sification. The magnitude of classification accuracy improvement with the inclusion of intramuscular data was consistent during single and parallel classifiers (between 3-15%).

Analysis of incremental DOF incorporation revealed the highest classification accuracy for a parallel classifier using combined strategy (1 DOF: 94.43%, 1+2 DOF: 85.4%, 1+2+3 DOF: 81.03%). Again, combined input from intramuscular and surface signals provided the most accurate classifier with the lowest reduction in accuracy with additional DOFs (Figure 3.13).

Classification accuracy for each individual DOF was significantly impacted by classifier strategy (Table 3.4). Combined strategy outperforms individual sEMG or

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	Single Classifier % (SD)	Parallel Classifier % (SD)	p-value
sEMG	75.91 (± 4.96)	66.85 (± 5.03)	< 0.001
iEMG	71.14 (± 6.94)	63.68 (± 6.69)	< 0.001
sEMG + iEMG (all channels)	86.23 (± 4.74)	81.04 (± 4.27)	< 0.001
sEMG + iEMG (PT/Sup only)	78.42 (± 5.48)	70.61 (± 5.48)	< 0.001

Table 3.3: Classification Accuracy for Single Classifier method versus Parallel Classifier Method for each classification strategy. The classification accuracies indicated are for all grasps, including one, two and three simultaneous DOFs.

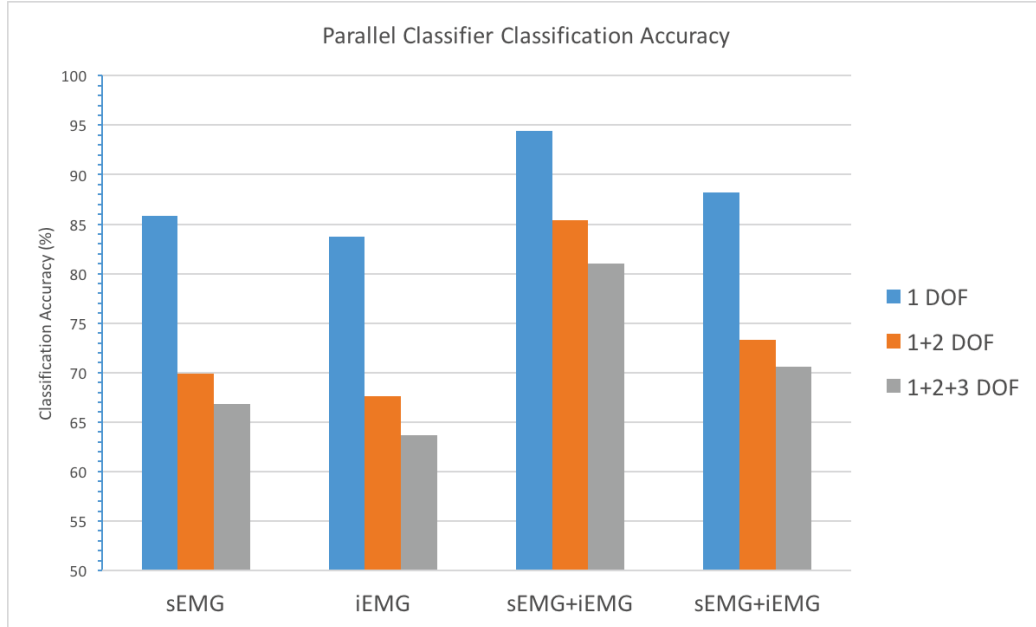


Figure 3.13: Examination of impact on incremental addition of DOFs on classification accuracy for a parallel classifier. As with surface, combined surface and intramuscular appears to be the most robust with additional DOFs.

iEMG classifiers for all DOFs. DOF3 (Wrist Pronate/Supinate) had the highest accuracy of all DOFs, regardless of classification strategy. Classification accuracy was higher for DOF2 and DOF3 with sEMG compared with iEMG; however, DOF1 has higher classification accuracy with iEMG.

3.4 Discussion

Surface and intramuscular EMG signals are often seen as competing methods for myoelectric prosthetic control. Within the literature, this is the first report to investigate the effects of instituting a combined control strategy using an array of intramuscular signals and surface signals. Previous reports have been limited to comparison of intramuscular-based control strategies to surface or with limited number of intramuscular electrodes.^{63,97} Combined classification involving only the Pronator and Supinator intramuscular signals with surface EMG largely focused on novel measures of usability, such as throughput and path efficiency, but improvements in offline classification accuracy have been reported.⁶³ The results presented here expand this research through the use of an array of 6 intramuscular electrodes. The accuracy improvements seen in both offline classification methods (parallel and single classifier) suggest that incorporation of global and local information may allow for better control of increasing DOFs, an issue particularly important when considering the development of increasingly advanced prosthetics.

	sEMG + iEMG % (SD)	sEMG % (SD)	p-value	iEMG	p-value
DOF 1	91.02 (± 3.96)	82.37 (± 2.73)	< 0.001	86.29 (± 4.20)	< 0.001
DOF 2	91.54 (± 4.13)	89.18 (± 3.14)	< 0.001	84.96 (± 4.40)	< 0.001
DOF 3	97.08 (± 1.41)	91.52 (± 2.61)	< 0.001	87.55 (± 4.21)	< 0.001

Table 3.4: Individual DOF classification accuracy. *DOF1*: Hand Open/Hand Close, *DOF2*: Wrist Extend/Flex, *DOF3*: Wrist Pronate/Supinate.

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Improved performance in a combined strategy likely results from targeting muscles involved in particular DOFs of interest. Previous work with intramuscular signals has demonstrated that targeted intramuscular electrodes result in higher classification accuracy than classifiers constructed based on signals from untargeted electrodes.¹¹² Classifier strategies that incorporate sEMG and signals from PT or supinator, muscles that typically more difficult to access and are attractive targets due to their high degree of crosstalk, result in higher offline classification accuracy compared with signals from sEMG alone.⁶³ The addition of muscles responsible for the control of hand grasps, wrist rotation and wrist flexion has resulted in an even greater improvement in classification accuracy than with limited targets such as Pronator and Supinator. The muscles presented here were prospectively selected based on the high likelihood of their continued presence following a transradial amputation. Identifying a higher number of muscle targets and incorporating their EMG signal dramatically improves classification accuracy in all classification methods tested.

Interestingly, when only pronator and supinator, as opposed to all intramuscular channels, were added to surface signals, the performance did not significantly improve over surface control alone. This may reflect the fact that with 27 DOFs, only a few involve supination and pronation and therefore just the addition of intramuscular information from pronator and supinator alone could not improve classification accuracy enough to increase the overall average. Alternatively, this may reflect the importance of placement position in these particular muscles, which more experi-

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ments are needed to test. Finally, the decreased classification accuracy may also be a function of the subject working to increase “stiffness” of the wrist, especially once the desired position was achieved. As discussed previously, this could result in concurrent activation of both supinator and pronator and therefore decrease the value of intramuscular electrodes within these muscles.

Particular movements were responsible for larger decreases in classification accuracy. In particular, movement class 15 (Hand Open, Wrist Flex and Wrist Supinate) and 18 (Hand Open, Wrist Extend, Wrist Supinate) were of interest. The two common movements with move 15 and 18 are Hand Open and Supinate. Together with the DOF data, it is likely that the drop could be from the addition of Hand Open in the setting of a supinated hand, since hand open/close was the DOF with the lowest classification accuracy. A combined strategy appears to be more robust when dealing with these combined movements. When all 1 DOF, 2 DOF and 3 DOF movements were incrementally examined, again combined classification in either single or parallel classification appeared to maintain the highest classification accuracy (i.e. most robustness) with the addition of each DOF. Additionally, one could potentially discard these two movement classes as they may have limited functional benefit. After excluding these classes, the overall classification accuracy for the combined strategy still outperforms sEMG-based classification (88.4% vs. 78.5%, $p < 0.005$). The robustness under different DOF conditions may also be helpful for future research exploring different load or limb position conditions, which are known to challenge surface-based

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algorithms.¹¹³

Previous literature has reported an increase in classification accuracy when utilizing parallel classification methods versus single classifier methods for surface signals.⁵⁸ However, these results require novel classification methods based on Bayesian classification, rather than traditional LDA, to accomplish this.⁵⁸ Even within novel techniques, despite allowing three parallel DOFs, simultaneous movement is limited at any one time to two DOFs. Classification accuracy with parallel classification has not been explicitly tested with intramuscular signals, but users demonstrate an increased ability to control multi-DOF Fitts' Law test with parallel classification compared to using a traditional single classifier or dual-site direct control.^{62,103} Unlike these previous studies, which examined parallel classification with surface or intramuscular signals alone, parallel classification with combined signals did not result in improved classification accuracy. This discrepancy may arise from the fact that, within this study, simultaneous classification was attempted for all three DOFs. Additionally, control of an on-screen cursor, such as what was done with Fitts' Law experiments, is a learned task that may not be readily translatable to directing prosthetic grasp and wrist movement, as was attempted with this experiment.

Examination of the classification accuracies for individual DOFs reveal impressive results for combined control of each DOF, with all accuracies consistently above 90% (Table 3.4). In this case, an individual DOF is different from decoding a single DOF, with the former representing a single hand movement, regardless of its involvement

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in multi-DOF grips. Interestingly, an untargeted surface array outperforms intramuscular signals for movements involving the wrist (rotation and flexion). Contraction patterns required for some wrist movements, particularly wrist flexion and extension, may help to explain why surface electrodes, which are capable of capturing signal from a wider area, may perform better than targeted intramuscular signals. Results with wrist rotation (DOF3) are surprising. An original hypothesis of this work involved the idea that intramuscular signals would be most useful for wrist rotation. It is possible that the electrode did not dwell near enough active motor units to provide better decoding. Despite their decreased accuracy decoding wrist rotation when used alone, it is clear that the incorporation of intramuscular signals into a combined paradigm dramatically improves the ability to classify wrist movement accurately (97.08 vs 91.52%, $p < 0.001$). An area of future work could be to remove the low accuracy testing sets prior to online classification strategy to see if overall classification accuracy improves.

The small conduction volumes for intramuscular signals may be particularly advantageous for some DOFs. Hand grasps may be ideal for intramuscular signal decoding, as intramuscular electrodes can sense small potentials within very confined conduction volumes.⁶⁰ Accurate control of up to four DOFs in the hand alone has been demonstrated using intramuscular electrodes.¹¹⁴ It is likely that intramuscular signals from large muscles can help to provide supplemental information that benefits surface based signals, such as the FDP and EDC for hand closing and opening,

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respectively. Indeed, when using combined signals for hand grasps, there was nearly a 10% increase in classification accuracy over surface alone and a 5% increase over intramuscular signals alone. Multiple intramuscular electrodes within the same muscle, in a combined strategy with surface, may allow for improved accuracy in such small movements as individual finger movements. Targeting separate muscles that often co-contract during a hand grasp may also result in improved accuracy. The improved classification accuracy with hand opening and hand closing using intramuscular EMG alone in this report may result from the use of APL, which is primarily responsible for thumb movement but is often contracted with wide hand opening.

The results presented here have implications for training strategies for both intramuscular and surface-based classifiers. First, this research has demonstrated a significant negative effect for using strong contractions for training a pattern recognition classifier. Not only were classification accuracies significantly lower (72.0 vs 86.79%, $p < 0.001$), but variability was also much higher (12.29 vs 4.55), suggesting an inconsistency with the signal from strong contractions. This is supported by early EMG literature showing variable firing patterns even with sustained forces above 50% MVC.⁷⁷ Traditionally, surface electrodes are given time to “settle” after being placed on the arm before classifier training is started.¹¹⁵ However, ideal duration after intramuscular placement has not been identified. If late signals differ significantly from signals obtained early after needle insertion, then classifier accuracy may change dramatically as a function of time from the training period. Results presented

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here between classifiers constructed within 10 minutes of intramuscular electrode insertion (early) and those constructed over an hour after electrode insertion (late) do not demonstrate a difference in the classification accuracy, suggesting that signals are stable following intramuscular electrode insertion.

Consideration of the pain caused by indwelling intramuscular fine-wire electrode is also of interest, since previous reports have suggested different motor unit firing patterns if the subject is in pain.⁸⁸ Also, it is possible that the muscle pain associated with prolonged placement was due to local edema or muscle damage that would further distort the signal. Review of the literature, however, has demonstrated that the small edematous layer formed around the electrode appears to serve as highly conductive layer that moderates the overall signal.¹¹⁶ Soreness caused by intramuscular electrode insertion does not appear to alter the signals significantly as classification accuracy between late and early signals were very similar, despite increased soreness during late trials.

There are several limitations to discuss that lend themselves toward future work. The residual muscles following upper extremity amputation may be highly variable. While the muscles were partially selected for their likelihood of being retained following transradial amputation, further testing with amputees would be necessary to see if these muscles retain their ability to provide signals helpful for generating a classifier. Additional testing with different target muscles may reveal differing results. For instance, in this research, FCU was used to supplement FDP information regarding

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wrist flexion. However, no such electrode existed for extensor action of the wrist, which is largely controlled by EDC. EDC has overlapping responsibilities, however, and controls extension of the fingers. Targeting of *Extensor Carpi Ulnaris* or *Extensor Carpi Radialis* may improve results. Placement of multiple electrodes within a single muscle may also allow for use of expanded hand grasps or proportional control.

Researchers have sought to explore the role of classification accuracy in the true usability of a prosthetic device.¹¹⁷ While it is likely that classification accuracy impacts prosthetic functionality, the ultimate usability is multifactorial. Previous reports on intramuscular parallel classification accuracy have focused on performance on Fitts' Law tests rather than online classification accuracy using virtual prosthetics.⁶² The lack of online classification accuracy determinations in this experiment preclude the ability to make determinations of whether a combined strategy would result in improved usability.

3.5 Conclusion

The use of combined control strategies with intramuscular and surface-based EMG signals results in improved multi-DOF classification accuracy with pattern recognition LDA. This strategy leverages the local information of intramuscular signals with the global information of surface-based signals and results in control improvements of approximately 10% over surface-alone classifiers. With increasing interest in im-

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plantable strategies, lessons learned from this research should be considered to inform electrode design. The final chapter of this thesis will discuss these future possibilities, in both the near term and beyond.

Chapter 4

Measuring Prosthetic Functionality

4.1 Background

Despite rapid advancements in both upper extremity prosthetics and their control algorithms, acceptance rates remain disparagingly low.³⁶ As outlined in Chapter 1, advanced upper extremity prostheses have not resulted in higher rates of regained functionality among upper extremity amputees, and still fewer than 20% of military service members who undergo an upper extremity amputation return to active duty.²⁴ Indeed, impaired functionality is a driving factor for abandonment for many prosthetic users.³⁷ One of the reasons for the disconnect between improved “in-lab” performance and consistently low acceptance rates may be the use of inadequate measures for prosthetic functionality when tested in the laboratory. Typically, classification accuracy is used as one of the primary measures for how well a prosthetic performs. However,

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all too often, the in-lab capabilities of the limb do not fully translate to a real world setting. In real world prosthetic utilization, amputees are more interested in accomplishing task-specific goals which incorporate object or environment manipulation, than they are in lab-based measures of classification accuracy.¹¹⁷

Efforts to measure the functionality of amputee patients in the clinical setting have become an area of increasing interest. Many of these measures have been adopted from the stroke population and their translation to amputee patients with myoelectric prosthetics is still being investigated. These tools, such as the Southampton Hand Assessment Procedure (SHAP), the Orthotics and Prosthetics User Survey Upper Extremity Functional Status (OPUS-UEFS), and the Trinity Amputation and Prosthesis Experience Scale (TAPES), provide quantitative measures of the subjective functionality associated with performing many common activities, such as ADLs and grasps of various objects.^{118–120} Many even have a component to separately judge the impact of the users prosthetic associated functionality on their quality of life.¹²¹ Validation attempts for some of these measures, such as the OPUS-UEFS, have identified components that do not apply to prosthetic users and have also suggested the addition of new items for prosthetic users.¹²² Additionally, tasks-based tests demonstrate widely varying degrees of responsiveness to recognizing performance changes with ongoing training, with an effect size ranging from zero to 1.59.¹²³ Further, they offer limited technical detail pertaining to the modifications that can be made to a complex control algorithm to improve user functionality and/or subjective sense of

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performance. Also, none of these protocols offer insight into appropriate patient selection for complex control schemes and may not be ideal test for novice prosthetic users.¹²⁴

To address this, new measures have been developed specifically for the amputee population. Resnik et al describe a novel measure, the Activities Measure for Upper Limb Amputees (AM-ULA), to evaluate task completion rates, movements speeds and even “awkwardness of movements” (as judged by a prosthetist) while using the DEKA arm.^{123,125} The QuickDASH (a modified version of the Disabilities of the Arm, Shoulder and Hand (DASH) survey) has also been recently validated in a small sample as an accurate tool to assess the user’s functionality following in-clinic, observed training.¹²⁶ Researchers are also exploring the development of virtual prosthetic training systems in which the user completes a virtual clothespin task and the classification accuracy of intended movements is tracked during the experiment.¹¹⁷ This initial interjection of more objective measures into the study of prosthetic “usability” during task performance did not demonstrate a strong relationship between classification accuracy and usability; however, more recent evidence suggests that control strategies that increase the classification accuracy above standard pattern recognition may increase task completion rates.^{117,127} Likely, examining classification accuracy alone is not sufficient to account for changes in usability and functionality associated with prosthetic usage.

Amputee use of compensatory movements has also garnered increased interest in

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recent tests to evaluate upper extremity functionality. There have been efforts to gauge the impact of wrist movements, such as flexion and extension, on prosthetic user's compensatory movements during task completion.¹²⁸ Some have suggested the incorporation of compensatory movements into the prosthetic design process, by gearing designs towards prosthetics that allow for more natural movements with fewer compensatory actions.¹²⁹ However, these efforts are currently lacking in their ability to provide user's specific data regarding trackable components of a movement that can be modified and targeted for modified training.

In this section, I will discuss the development of a novel tool known as the Prosthetic Hand Assessment Measure (PHAM) for measuring prosthetic functionality. The goal of the PHAM is to provide quantitative methods for assessing the usability of a prosthetic and to calculate the impact of advanced classifiers and new training methods, on amputee functionality during task performance. This will be accomplished through the integration of a motion and grasp tracking system with a unique grasps and wrist-based tasks. I will provide results from initial testing with able-bodied subjects, highlighting the difference in performance measures between movements performed with and without a prosthesis. I will then discuss the implications these findings may have for patient-specific algorithm selection and training methods.

4.2 Methods

4.2.1 PHAM Overview

In order to generate data with increased utility while testing the functionality, the PHAM was developed as an in-office and at-home tool for myoelectric prosthetic users. The original concept draws inspiration from the clothespin test, in which a user must move a horizontally oriented clothespin to a vertical pole. This test was chosen as it involves movement in multiple DOFs to complete the task and has been implemented previously for the amputee population in both the clinical and virtual settings.^{117,130} However, the current implementation of the clothespin tasks allows for completion time and rate measurements only, and therefore lacks specific information regarding aspects of the movement that are causing significant delays. As mentioned previously, there have been some investigations into the use of tracking classification accuracy during the clothespin task.¹²⁷ While this may provide some look into the relationship between classification accuracy and usability, it does not take into account the other aspects of a user's movement, including the path taken and the use of any compensatory movements. Therefore, the PHAM was additionally designed to provide motion tracking during a task, transmitting information regarding the arm and hand position for movement analysis. Finally, the PHAM would provide two additional measurements not currently reported on in the literature: hand path length and arm energy usage. The motivation behind the

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inclusion of these two elements was to increase the number of quantifiable outcomes that could be compared between different control strategies and training paradigms. Namely, if a certain training approach decreased overall path length and energy usage to such a level that it approximated normal subjects, this may have a positive effect on the overall usage and perceptions of functionality amongst prosthetic users. By generating individual results for each user, these data could also be used to generate user specific training paradigms.

Herein I present the original design and preliminary results comparing normal-limbed users to able-bodied users with a modified prosthetic limb without wrist motion. Such a comparison allows for an initial determination of the compensatory movements among an amputee population with only one DOF (hand open and hand close). It was hypothesized that there would be a significant increase in the associated energy consumption and path length due to compensatory movements around the shoulder. As a proof of concept, it is necessary to show this increase first to further explore the hypothesis that a factor other than classification accuracy could be contributing to movement differences, and likely low acceptance rates, among prosthetic users.

4.2.1.1 Physical Setup

The PHAM physical unit consists of three horizontal beams and three vertical beams, arranged to form a window-pane type of a configuration that allows for 6

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possible clip locations in both the horizontal and vertical directions, for a total of 12 clip locations (Figure 4.1). The overall height is such that the midpoint is at the user's chest. For our purposes, this was approximately 110 cm, though the height is adjustable via sliding mechanisms on the side of the strut supports. Within this setup, the clip locations are started on the middle for locations (2 horizontal and 2 vertical). Practically, it means that the user must change the position of the wrist when moving from grasping a horizontal clip to a vertical clip. The start/stop button is attached to an Arduino® R3, which controls an automated timing function and toggles the end-point LEDs to direct the start and stop location of the clip for the experiment. The testing software was developed using Python, allowing for computer-based setup of testing movements and recording of output parameters. The software starts the experiment with the push of the start/stop button. It then prompts the user to move the clip from one lighted location to the end-point LED location (Figure 4.2). Once the user has moved, the start/stop button is pushed again and completes that movement.

4.2.1.2 Motion Tracking

Arm movement and motion tracking was completed using an array of 9-axis Inertial Measurement Units (IMUs) (MPU9150 Nine-Axis MEMS Motion Tracking Device). There were a total of 4 IMUs, which were affixed to the mid-anterior chest, the arm at mid-distance down the humeral shaft, the mid-forearm and finally the

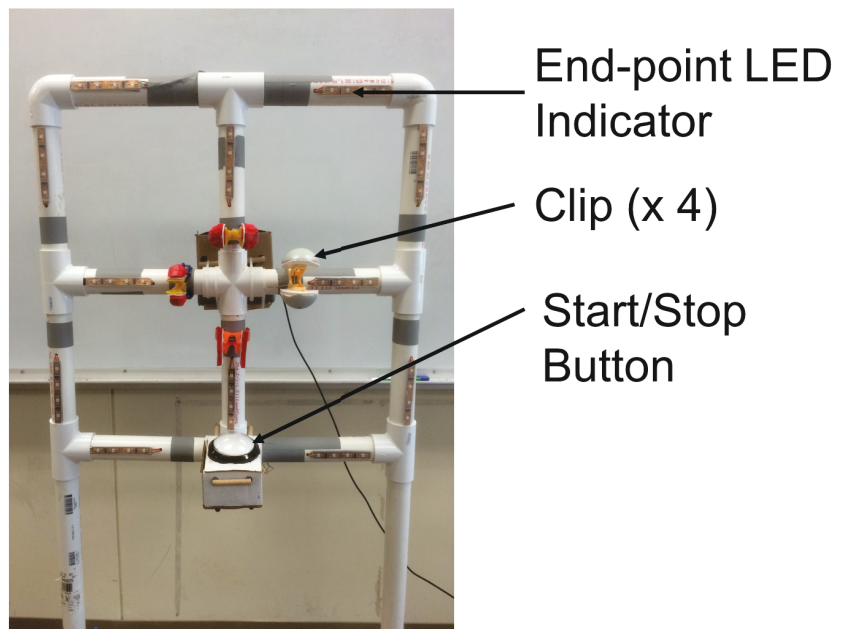


Figure 4.1: Physical construction of the PHAM unit. Each end-point LED indicator represents a possible clip location at the endpoint of an experiment. There are a total of 12 possible locations, with 6 horizontal and 6 vertical. There are 4 clips which must be moved to complete an experiment. A start/stop button is user controlled and allows for time tracking during each movement.

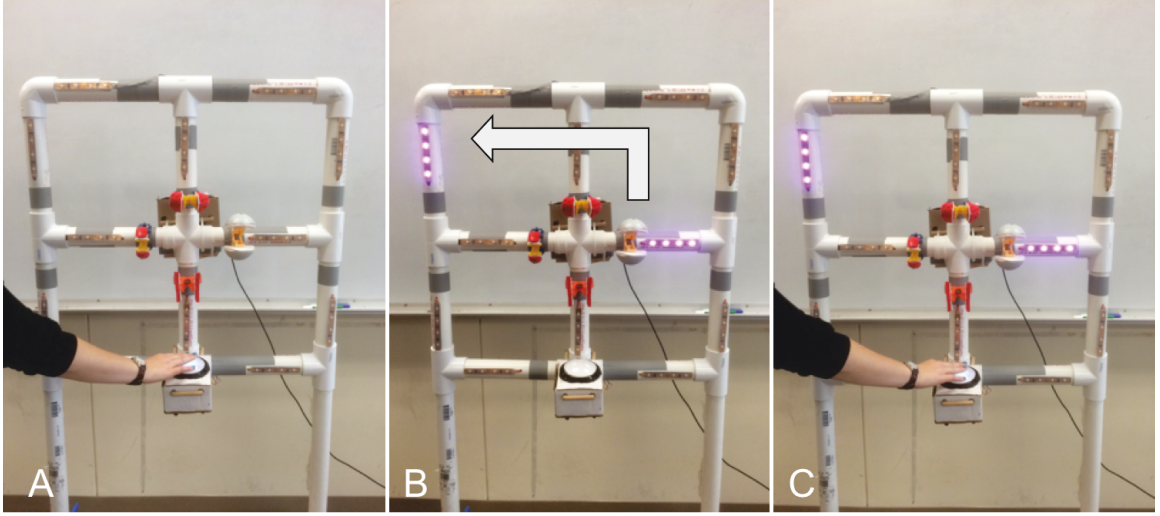


Figure 4.2: Movement experiment using the PHAM. To start, the user pushes the start/stop button (*A*), which illuminates LEDs indicating the clip to use and the location to which it should be moved (*B*). The gray arrow denotes the direction of the movement. The user then presses the start/stop button again to complete the movement (*C*). Each experiment consists of four movements.

hand. Position data from each IMU was read simultaneously through a Teensy® 3.0 micro-controller and recorded in a continuously updated array within the Python script. Following the experiment, the array was then processed offline using a separate Matlab script for energy and path length determinations (Appendix). Within this script, the chest was used as the reference vector, such that all recorded movements were based around the shoulder. This allowed for easier measurement of compensatory movements around the shoulder, but did lead to the possibility of missed compensatory movements with other body segments, including the hips and legs. The resultant output could be deconstructed into movements involving only X, Y and Z individually or could be mapped three dimensionally, divided into individual actions (i.e. divided by button presses on the start/stop button on the PHAM) (Figure 4.3).

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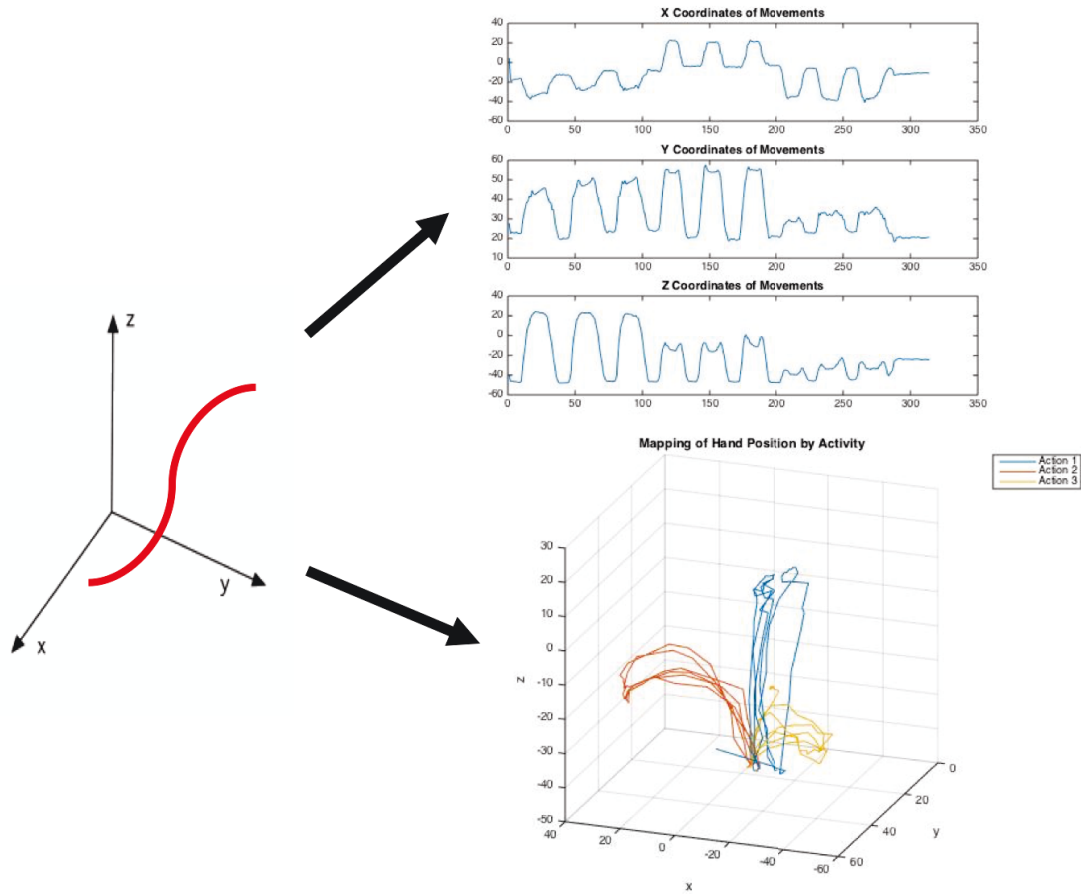


Figure 4.3: The figure depicts an imaginary movement recorded by the PHAM IMUs during a mock reach task. During this task, the subject reached to three different locations (Actions 1, 2, and 3). The movement takes place in three dimensions but can be tracked as either individual x, y and z positions or in three dimensional space. The trace demonstrates the precision of the output in all three axes with the IMU system. The combined output of the three x, y and z directional traces is seen in the bottom right figure. In three dimensions, the movements can be divided based on presses of the start/stop button.

4.2.2 Clinical Testing

Four able-bodied subjects were enrolled to start preliminary testing on the PHAM. For this experiment, the able-bodied subjects were tested on two separate days to reduce the learning effect on prosthetic performance. Participants were first asked to complete 24 sets of 4 movements using their intact limb. Limb position was tracked using the previously described IMUs. At the completion of 8 sets, the subject was prompted to rest, if desired, to reduce the effect of fatigue on late-trial movements.

On the second day of testing, individuals were fitted with a modified prosthetic and a bebionic hand (RLSteeper, Leeds, UK) without any wrist articulation (Figure 4.4). Modified prosthetic fitting, as opposed to splinting rotation of the able wrist, was performed to appropriately replicate any adverse effects of movement of the prosthetic during the task.¹³¹ The subjects were then given direct control over the hand open and hand close mechanisms with surface EMG signals from 2 paired electrodes on the ventral and dorsal sides of the wrist. Signals were amplified with 13E200 MYOBOCK amplifiers (Ottobock, Plymouth, MN). Prior to the start of the recorded movements, participants were allowed to test their ability to control the prosthetic and make any electrode position changes necessary to improve performance.

For the purposes of this testing, the focus was to examine compensatory movements around the shoulder in terms of energy usage. Therefore, the primary outcome measures were hand path length and energy expenditure of the arm. Energy expenditure was calculated based on changes in potential energy changes and force required

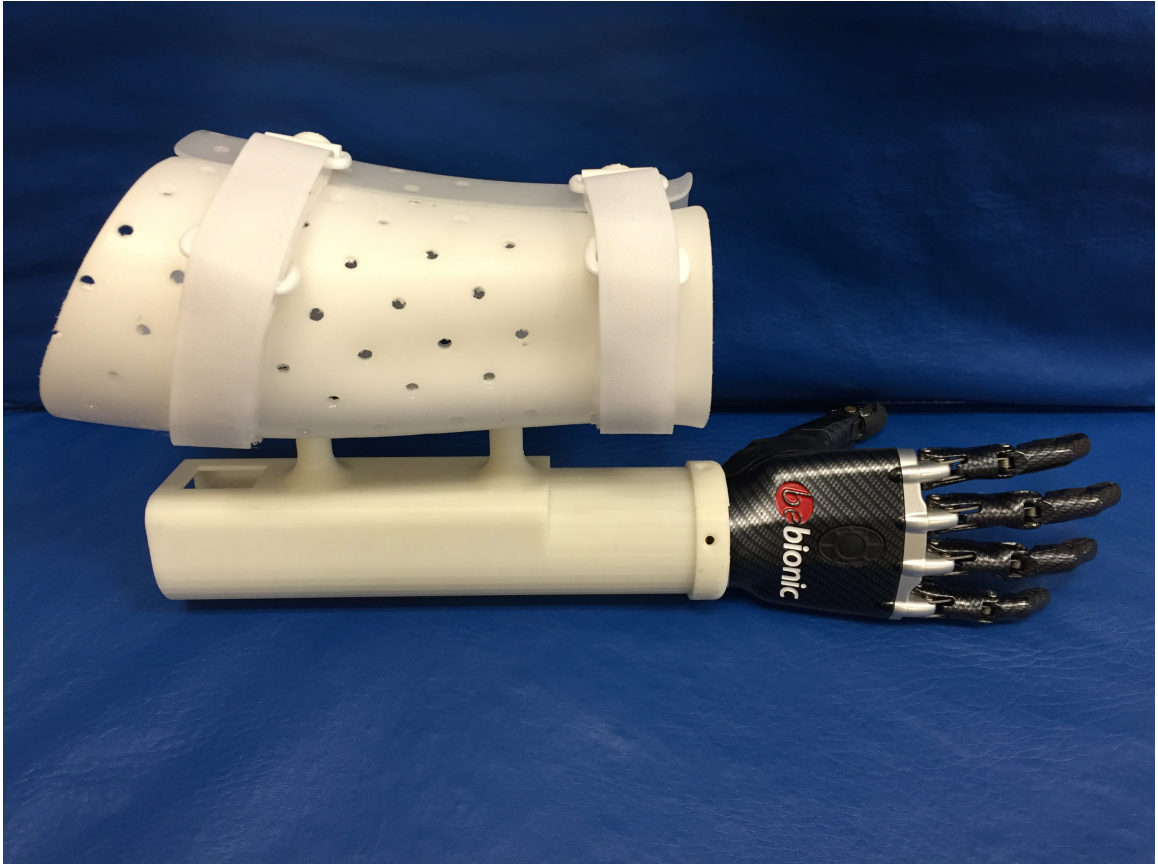


Figure 4.4: Modified prosthetic device for able-bodied experiments with direct control of prosthetic hand. The superior aspect is affixed to the intact forearm, over the electrode array used to capture EMG signals. The connector for the hand also houses the amplifiers for the EMG signals and the battery. The unit allows for wrist rotation if such a model is attached, though this was not done for the purposes of this experiment.

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to move the limb the recorded distance (Appendix B). Additionally, completion rate and time was recorded. A trial was deemed “successful” if the stop button was pressed prior to a 30 second elapse. For movements that went beyond 30 seconds, the user was allowed to complete the movement if desired, though the final time recorded was 30 seconds. If the clip fell during the course of the experiment, it was reset to the starting position and the user was granted an additional attempt, though energy and path length were aggregate for the movement. Any movements that went beyond the 30 second time limit were no longer included for analysis and termed a “failed” movement. Further, since comparison were intended to be carried out in a pair-wise manner, the corresponding movement with the intact limb was also removed from analysis. Statistical analysis was performed using paired, two-tail t-tests for continuous variables. When comparing outcome measures, pair-wise comparison was used to calculate changes for each user prior to calculation of an overall average to allow for baseline differences in movement patterns between participants.

4.3 Results

All four subjects were able to complete all 96 movements within the 30 seconds for the intact limb. When using the modified prosthetic with direct control hand, there were 4 failures for Subject 1, 5 for Subject 2, 1 for Subject 3 and 3 for Subject 4. For these movements, the IMU and timing information from the corresponding

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Outcome (per movement)	Able-Bodied	Modified Prosthetic	Change	p-value
Completion time	4.06 s	12.5 s	307%	< 0.001
Hand Path Length	4.68 m	9.52 m	203%	< 0.001
Elbow Path Length	3.50 m	6.08 m	173%	< 0.001
Energy Usage	83.76 J	140.54 J	70.8%	< 0.001

Table 4.1: Outcome measures for PHAM study from able-bodied participants using intact limb and modified prosthetic.

trial were also dropped. Further, IMU data was incomplete for trials 2-6 for Subject 2, due to improper initialization of the IMUs during this block. Therefore, these data were excluded in the modified prosthetic and intact limb trials. For all subjects, the final movement was dropped due to inconsistent tracking of complete movements. Therefore, complete data were obtained in 68 movement pairs for Subject 1, 52 movement pairs for Subject 2, 71 movement pairs for subject 3 and 69 movement pairs for Subject 4.

Compared with intact limb movement, use of a modified prosthetic without wrist movement resulted in a significant increase in energy expenditure (Figure 4.5). Overall, energy expenditure was increased by 70.8% per movement when using the modified prosthetic compared to intact limbs (Table 4.1). Hand path length was approximately doubled when comparing modified prosthetic usage to intact limb. Elbow path length also increased significantly (average 73%/subject), though less than concurrent hand path length increases. Additionally, completion time was significantly increased as well, by over 300%.

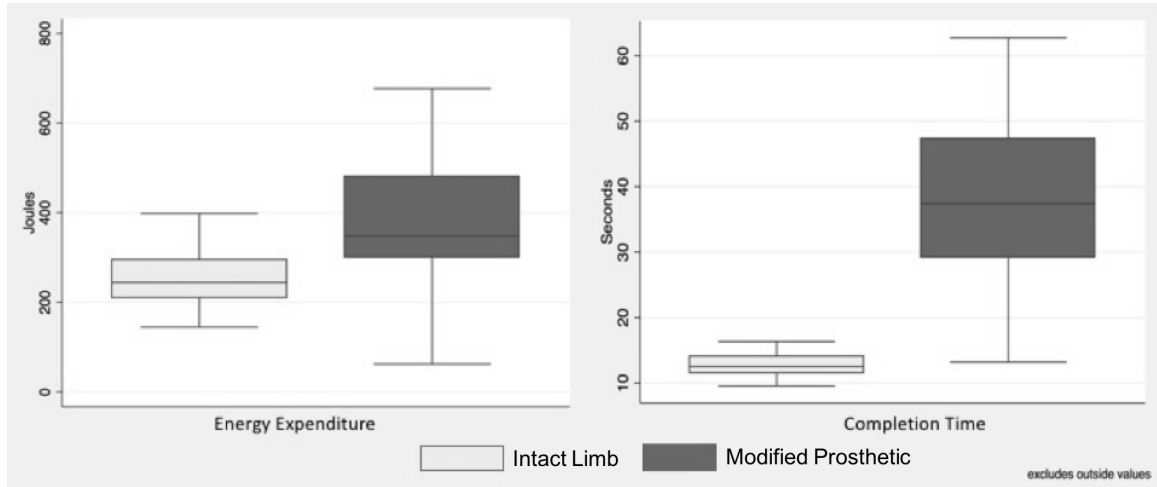


Figure 4.5: Results comparing energy usage and completion time with intact limb (before) and with modified prosthetic (after). Both outcome measures demonstrate a statistically significant increase. Both outcomes also demonstrate an overall wider distribution, suggesting there may be a greater difference in control abilities as well as potential compensatory movements between subjects in the prosthetic group compared to when using their intact limb.

4.4 Discussion

As the complexity of upper extremity prosthetics increases, so too must our ability to measure their usefulness. Functionality tests must come to involve factors other than subjective factors or limited objective measures, such as completion time and classification accuracy. Not only has the classification accuracy demonstrated questionable predictive power for the usability of a prosthetic, but also limiting information to these factors may miss a large opportunity for utilizing novel measures to track prosthetic functionality.¹¹⁷ For upper extremity amputees, the use of compensatory movements may represent decreased functionality due to limited mobility or poor prosthetic usability. Intuitively, the use of compensatory movements suggests

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an “unnatural” aspect to the movement and therefore represents a useful target for examining the usability of a prosthetic. It was with this motivation that the PHAM was developed. Here, the preliminary results are presented demonstrating the ability of the PHAM to track energy usage and the impact of a non-functioning wrist on subsequent energy usage.

Currently, studies are limited regarding the use of compensatory movements in upper extremity and most involve the use of expensive digital motion tracking systems with a series of cameras.¹³² However, the PHAM provides motion information, including shoulder angle, elbow angle, hand path and arm path, with the use of an inexpensive array of IMUs. We have demonstrated the ability to collect user-specific information during a complex, multi-DOF task that involves reaching and grasping. The output of this system can be tailored for clinical use, depending on the requirements of the therapist and the user. For instance, an example output may display the path the user took, the energy required to take that path, and the time and locations the user’s hand was in an “open” configuration, allowing the prosthetist to track hand close/open functionality at multiple locations (Figure 4.6). Additionally, the information could be stored in a user-specific file that allows for longitudinal tracking of performance. Finally, the data could be used to assess a user’s response to different training paradigms. In this circumstance, one could imagine an amputee reporting difficulty with wrist rotation, especially when reaching. The therapist would then help devise a training schedule that focused heavily on wrist rotation, perhaps plac-

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ing less emphasis on elements the user feels they have mastered. Such a schedule would maximize the time a user spends on elements of the prosthetic that ultimately result in lost functionality. Following the training schedule, the user could complete the task again and the metrics listed previously would be available for comparison to pre-test levels.

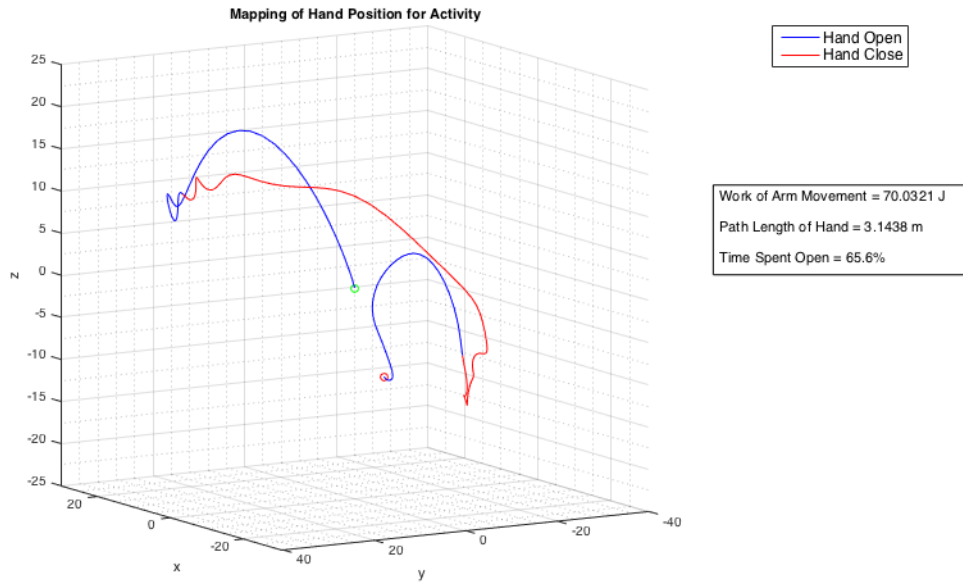


Figure 4.6: Example output during intact limb movement completing a reach and grasp tasks with the PHAM. The output displays the trajectory and the hand configuration (i.e. opened or closed) at each location. The starting point is denoted as a green circle and the end point is denoted as a red circle. Further, quantifiable outcomes such as Energy Expenditure (Work of Arm) and Path Length are included within the output (see black box) to allow for contextual interpretation of the path compared to previous user movements to complete the experiment.

Indeed, many compensatory movements may be associated with significant increases in required energy expenditure. In a study of a cohort of transradial and transhumeral amputees completing a series of reaching and grasping exercises made

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to approximate ADLs, Metzger et al demonstrate an increase in both truncal and shoulder movements.¹³³ Both of these segments involve large percentages of total body weight and their increased movement therefore represents an increased energy usage. Not surprisingly, increased load bearing, as happens with the prosthesis, increases the energy usage for moving a certain segment, which may account for a portion of the energy increases seen with modified prosthetic usage in this experiment.¹³⁴

Another reason for increased energy consumption among amputees may be the inability utilize all muscle synergies due to atrophied muscles or altered internal models of control. Though examination of these internal models is outside of the scope of this thesis, new internal models of movement, including patterns of reach and grasp, have become an area of research.¹³⁵ Synergistic muscle movement has recently been shown to potentially decrease upper extremity energy consumption, based on computer models.¹³⁶ Traditionally, the central nervous system (CNS) develops an optimal trajectory to limit metabolic expenditure with reaching movements; however, our results indicate a significantly altered path length resulting with modified prosthetic use.¹³⁷ The change in path length may be the result of poor CNS planning in subjects not familiar with prosthetic usage, or may be the direct effect of limiting wrist movement. Longitudinal measurements after repeated training sessions could evaluate the ability to develop at new “optimal” for amputees.

The study of energy expenditures with prosthetics has become popular in lower

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extremity amputations.¹³⁸ In this population, the ability to relatively high levels of energy output is a predictive factor for successful prosthetic usage.¹³⁹ However, as with our research, the question remains, are more energy efficient or economical movements favored highly enough to impact prosthetic acceptance rate? At least some argue that, without that answer, compensatory movements should still be taken into consideration for prosthetic design.¹²⁹ Additionally, path length increase was much greater than energy increase. This may suggest that despite a greater total path length (as measured from the hand), there is an attempt to improve the efficiency of movement when confronted with a impaired joint.

Wrist movement is an essential component to multi-DOF prosthetic design, and represents a consistent desire among prosthetic users.^{37,140} In general, prosthetic users perceived less shoulder movement when their prosthesis has some capability for wrist movement.¹⁴⁰ The literature regarding the quantifiable impact of wrist movement on functional outcomes is mixed. Some evidence suggests wrist flexibility may improve functional assessment scores compared with static wrists, though the benefit may be modest (score of 83/100 vs 80/100).¹⁴¹ However, recent measures have not demonstrated a link between increased wrist flexibility and functionality; though, notably there was a perception of more intuitive movement with the addition of wrist control.¹²⁸ One reason for these differing conclusions may be the outcome measure of interest; namely, completion of previously reported functionality measures may not accurately capture the benefit afforded by the addition of wrist movement. Based on

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our results, the use of an upper extremity prosthetic device without wrist movement results in nearly a doubling of the energy usage compared with an intact limb. Hand path length and completion time are both significantly increased as well. Given the high impact of wrist movement on PHAM outcome measures, it could be a useful tool to evaluate the impact of the combined strategies mentioned in Chapter 3, which have a high classification accuracy for wrist rotation. The PHAM offers the opportunity to test the impact of prosthesis capable of additional DOFs on energy expenditure, as well as giving the capability of testing the impact of new control strategies on these measures.

Further, compensatory mechanisms increase the variability of movement patterns during task completion.¹³² In our study, we have demonstrated a large increase in both the average path length (9.52 vs 4.68 m/movement, $p < 0.001$), but also the standard deviation of these paths (4.38 vs. 1.88 m, $p < 0.001$) in the modified prosthetic group, suggesting that movement variability is increased in a group with no wrist movement and EMG-based, direct control of hand movement. Interestingly, transradial amputees demonstrated changes in elbow movement during task completion, despite having an intact elbow, suggesting that factors beyond the joint of interest affect the use of compensatory movements.¹³³ In our study, we saw elbow path length increase, though to a lesser degree than hand path length (173% for elbow, 203% for hand). These results suggest that amputees may attempt to maximize elbow position during a movement.

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Studying the movement patterns may also allow us to evaluate a user's feedforward model, in which the brain alters kinematics to account for the prosthetic. Able-bodied users utilize a combination of feedback (such as proprioception) and feedforward (knowledge of intended location) to generate a successful movement. However, amputees are often missing the feedback component, and can have difficulty with movements in which they are not allowed to visualize the arm. Therefore, completion of motion-tracking and energy-tracking experiments, such as the PHAM, with sighted and blind-folded amputees would allow for potential study of the feedforward system because differences in the performance patterns between the two conditions would be due entirely to the visual feedback system. Evaluation of the feedforward system has been suggested as means to study cortical reorganization and internalization or acceptance of prosthetic.¹⁸ Exploration of the kinematics of movement may also help to explain usage differences in body-powered versus myoelectric prosthesis for certain users.¹⁴²

4.5 Limitations

It is important to identify some of the key limitations in this study. The first limitation would be the inability to account for hand opening and closing in the current model. Originally, two flex sensors (FS7548) were attached to the setup and programmed to provide an indication of open or close status based on resistance.

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However, during preliminary trials, these sensors created inconsistent measurements due to insecure fixation on the hand. Therefore, these sensors were abandoned for testing purposes. However, hand grip could be determined in two additional ways. The first would be to track the output of the classifier (Hand Open vs. Hand Close) and create a time-based array that allowed for correlation of that status with IMU data. The second mechanism would be to look at servo motor power requirements to determine if the hand is closing. This method has the added benefit of being able to detect if the hand closure results in grasping an object and if that grasp requires a significant power increase in the hand. Another important limitation is the method in which energy is calculated. Currently, energy calculations are based on changes in potential energy and do not include additional forces such as drag or inertial energy. While the air drag may be a negligible force and therefore not require incorporation, inertial costs may have a significant impact on the potential type of motion a user takes. Recent literature has demonstrated that an internal model of movement costs can drive movement intensity and direction.¹⁴³ A more thorough examination of these factors may elucidate confounding factors that explain energy differences between normal, intact limb and prosthetic movement patterns.

4.6 Next Steps in Functional Assessment

There are several additional avenues of research made evident by this project. Currently, the interpretation of the PHAM is limited to compensatory movements about the shoulder, using the chest IMU as a reference. However, given the evidence of torso movements as a component of compensatory movements for upper extremity amputees, future iterations would likely benefit from including an additional reference point and calculating torso movement during the exam.^{129,133} Tracking chest movement may also allow for more accurate determination of shoulder movement and overall energy expenditure in the cases where the subject moves their entire body to complete a task. Further, tracking elbow joint angles during the experiment may provide insight into difference in arm configurations between prosthetic users and able-bodied subjects. Additional testing is necessary to determine if ultimately decreasing the energy consumption for a movement will improve prosthetic acceptance. To complete this study, enrollment of several amputees in various stages of prosthetic usage would be necessary, as well as an accepted training regimen that focuses on user-specific components that reduce functionality. Multivariate analysis would also be necessary to remove confounding factors between energy usage and prosthetic acceptance.

The PHAM is currently limited to reach and grasps motions. However, as our understanding of compensatory movements grows, we have seen that the change in such movements and associated energy expenditure may also depend on task type.¹²⁹ As

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such, implementing additional movement types may help to improve our understanding of prosthetic compensatory movements. For instance, measuring energy output while performing ADLs could potentially allow for implementing these quantitative measures during tasks that are deemed most important to the user.

The ultimate goal of the PHAM would be to apply quantitative outcome measures, such as energy usage, path length and task completion times, to otherwise subjective measurements of functionality. There are at least two areas for future development that would benefit from this strategy. The first would be as a method to test the efficacy of new control algorithms, such as the combined methods listed in Chapter 3. The Target Achievement Test has been similarly used as a mechanism for comparing accuracies of control strategies in Targeted Muscle Reinnervation (TMR) patients.¹⁴⁴ However, this test only provides information regarding ability to achieve a desired position rather than information regarding actual task completion. Since amputees may develop unique strategies to accomplish a goal compared to those with an intact limb, a measure, such as the PHAM, which provides extended information regarding the additional measures of energy usage and hand path length, may improve the ability to distinguish between two control strategies.¹³² In addition to evaluating control strategies, the PHAM could be useful judging the efficacy of training paradigms. The impact of training itself on overall prosthetic functionality has led to the development of novel control strategies, including virtual training and prosthetic-guided training.^{145, 146} Real quantitative feedback that can be tracked longitudinally could

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augment subjective user feelings of increased functionality and prosthetic acceptance with a particular training strategy. Likely, the combination of quantitative outcome measures, provided by mechanisms such as PHAM, and qualitative measures, such as quality-of-life questionnaires, will provide the best mechanism for enhancing user functionality and prosthetic acceptance.

Chapter 5

Future Directions

The research presented here has demonstrated the benefit of combined information from a surface-based electrode array and intramuscular electrodes within multiple forearm muscles for the control of prosthetic limb with multiple degrees of freedom. However, in order for users to realize the full potential of this system, many of the concerns with both approaches will have to be addressed, including practical ones such as electrode shift and signal loss due to sweat-skin interface for surface electrodes, and the invasive nature of intramuscular electrodes. Further, patient convenience and acceptance of the prosthetic control method must be heavily considered, as prosthetic adoption continues to be abysmally low despite advances in control accuracies.²⁰ In this chapter, I will present my view of the future of EMG-based prosthetic control from the perspective of both a clinician and a researcher in the field.

5.1 DARPA and the HAPTIX program

The Defense Advanced Research Projects Agency (DARPA) has been a constant driver of forward-thinking design in the world of upper extremity prosthetics. The “Revolutionizing Prosthetics” program, launched in 2006, has been a call to arms for the upper extremity prosthetics community, which has long lagged behind its lower extremity counterparts. In the 10 years since its inception, research directly supported by the program has led to the development of two anthropomorphic arm systems, the DEKA and the MPL.¹⁴⁷ Indeed, its longevity and persistence as a DARPA initiative is a huge testament to its impact, both potential and realized, on the lives of service men and women.

One of the most aggressive new frontiers for the “Revolutionizing Prosthetics” campaign is the Hand Proprioception and Touch Interfaces (HAPTIX) program, with the intent on designing smarter prosthetics that “provides movement and sensation like a natural hand.”¹⁴⁸ Indeed, the HAPTIX program represents an expansion of the “Revolutionizing Prosthetics” scope, to providing both intended movement decoding and proprioceptive and sensory feedback that can improve the experience of operating an upper extremity prosthetic. Peripheral nerve stimulation has become an area of intense focus for restoring lost sensory function.¹⁴⁹ Through the implantation of cuff electrodes on sensory nerves, researchers have been able to use patterned stimulation of the peripheral nerves to yield sensations of the phantom limb.¹⁵⁰ Two subjects equipped with peripheral stimulation report improved confidence and performance

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during blindfolded tasks, even approximating sighted performance on some tasks.¹⁵¹

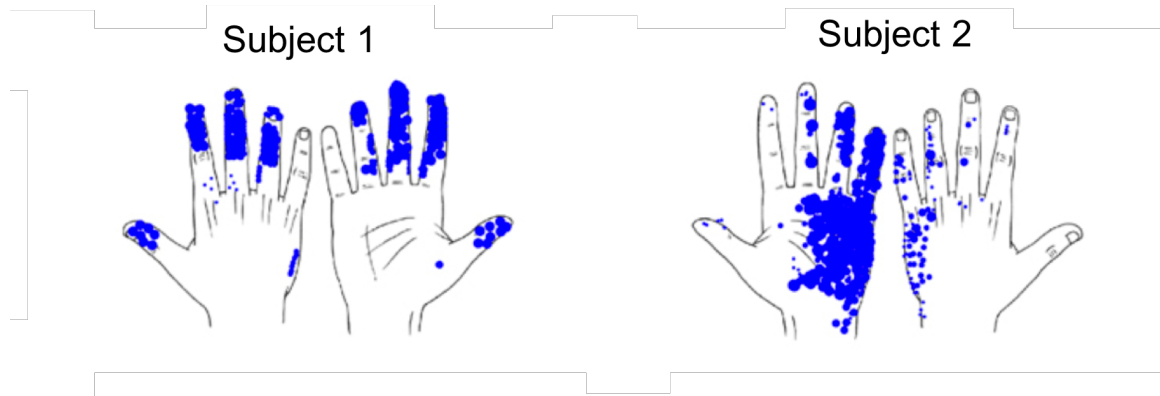


Figure 5.1: Phantom limb sensation with peripheral nerve stimulation differs significantly between patients. The two patients presented here have identical stimulation on the median and ulnar nerves. The resulting sensation patterns, however, are highly variable.¹³

While exciting, it is important to recognize peripheral nerve stimulation is in its infancy. Patterns of stimulation vary from patient to patient, including variable distribution of phantom pain sensation (Figure 5.1). Also, the “input” depends highly on the type of sensor on the prosthetic itself. There have been multiple types of sensors used for instances such as slip detection, but sensors with a fully human resolution and response range are lacking.^{152–154} Work in our lab by Luke Osborn may yield more natural touch sensors that enhance the performance of peripheral nerve sensory feedback.

Alternative uses, such as decoding of muscle signals, may be easier targets for perineural systems placed on peripheral nerves.^{155,156} In the lower extremity, perineural systems have been used in Functional Electric Stimulation (FES) to stimulate the femoral nerve to result in leg lifting and standing.^{157,158} However, perineural decod-

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ing and stimulation in the upper extremity is much more limited. Recent exploration of in-dwelling, high density Utah Slanted Electrode Arrays placed on the ulnar and median nerves has demonstrated a moderate ability to control up to 13 different finger movements after extensive training.¹³ However, online decoding in these same subjects was limited to two movements only, below the capability of current surface-based systems. Nerve-based stimulation systems have even been posited for more central use, with epidural stimulation for neurospasticity of the lower extremity.¹⁵⁹

In my opinion, perineural systems have two huge appeals compared with muscle based systems. The first is the ability to decode forward movements and encode resultant stimulation simultaneously via interaction with the median and ulnar nerves.¹⁶⁰ Not only does this limit the necessary hardware and surgical intervention, but also it hints at an interaction of the efferent and afferent information that could improve the naturalness of movement. The second is the ability to decode movements from muscles that are no longer present, including intrinsic muscles of the hand those of the forearm lost to the amputation. The extreme limitation here is that these areas must maintain their cortical representation in order to even drive peripheral stimulation or correct interpretation of returning sensory signals. However, for patients that meet these criteria, peripheral nerve decoding and encoding represents an exciting area of advancement towards the HAPTIX goal of restoring naturalness with prosthetic limbs.

5.2 Advanced Implantables

Regardless of the site of stimulation and/or sensation, the movement towards a fully implantable system has significant appeal. I have previously presented the IMES system, which has been fully implanted through a research collaboration by the Alfred Mann Foundation and Walter Reed (Figure 5.2).^{12,14} These implantables certainly stand on the border of the state-of-the-art and the futuristic. In some ways, however, these only represent an incremental improvement over the current strategies, and do not have the ability to account for the improvements of a combined method, as discussed in this report. The following discussion, therefore, will focus largely on exciting new techniques, whose clinical viability has yet to be proven but have the possibility of shifting the paradigm of prosthetic control.

One project selected for this task involves a collaborative effort between a commercial entity (Ripple Neuro, www.rippleneuro.com) and two universities, University of Pittsburgh and Case Western Reserve University.¹⁵ The team aims to develop an implantable system with recording from muscles through the use of electrodes seated within the muscle bed in the residual limb (Figure 5.3). And it has garnered the interest of DARPA, snagging a \$5.9 million Phase I award under the HAPTIX grant. The system consists of two devices. The first is an implantable 32 channel high-bandwidth electrode array, with individual electrodes lying within the muscles of the residual limb. The second is an additional implantable array, this time with 64 channels, tasked with stimulating the peripheral nerves for the tasks of providing sensory

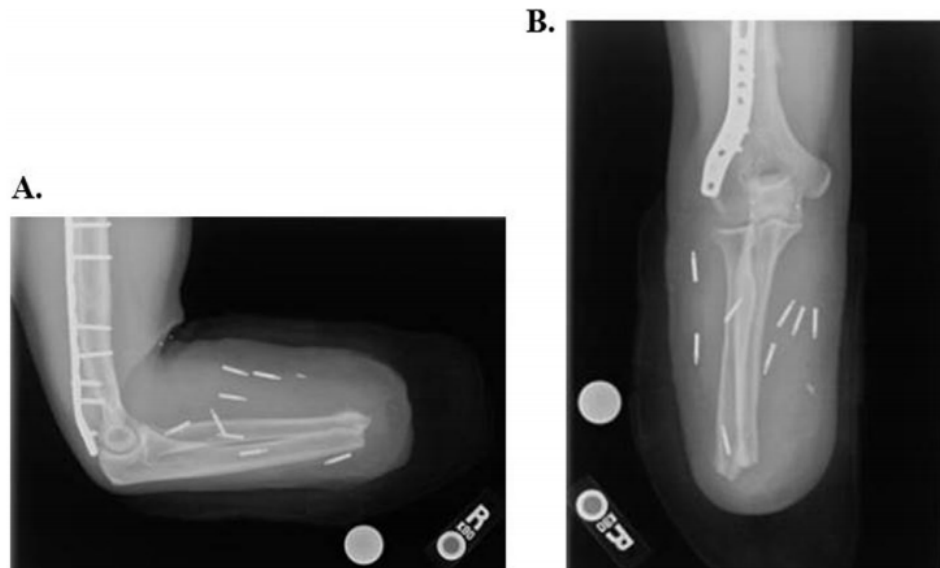


Figure 5.2: Implantable electrodes within the residual limb of an upper extremity amputee. Electrodes are radiopaque and appear white on the X-ray. The transverse images (A) help to identify which electrodes are within posterior and anterior groups. The anterior images (B) help to localize the laterality. As seen here, there is no method to troubleshoot problems based on radiographic findings.¹⁴

feedback. The system envisioned as such leverages the benefits of decades worth of EMG based research and control algorithms, with cutting edge developments in nerve stimulation.

An important aspect of considering fully implantable systems is identification of appropriate electrodes. Recent large animal trials have demonstrated the biocompatibility and reliability of signal transduction from a multichannel implanted array with inductive coils used for data transmission.¹⁶ Though this model was interested primarily in demonstrating efficacy for high-level amputations, the idea of multiple channels “tentacled” out to receive signals from muscles distributed around the forearm and then return that signal to a central transducer for communication with a

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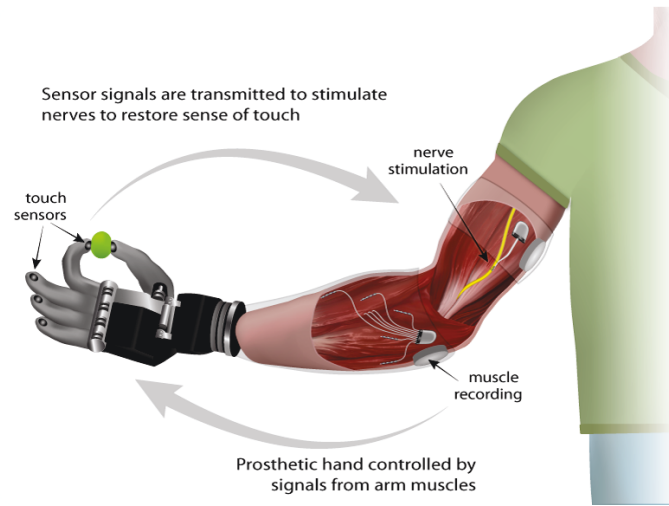


Figure 5.3: Proposed design for implantable system that allows for sensing of intramuscular signals from implanted electrodes within the muscle beds and proprioceptive feedback applied directly through stimulation of an efferent nerve. The system is a proposed solution to the DARPA HAPTIX project through a joint effort of Ripple Neuro, University of Pittsburgh and Case Western Reserve University. The entire unit would communicate to the prosthetic socket through wireless power and data transfer from an implantable unit directly beneath the skin.¹⁵

prosthetic controller has broader implications (Figure 5.4). Certainly, within the context of the research presented here, obtaining signals from multiple muscular sites has an advantage over surface based control. Additionally, having the electrodes hardwired together prevents any issues with syncing from multiple high bandwidth individual sensors.

One of the major points of this work has been the benefit combining global EMG information from surface electrodes with local, muscle-specific EMG information from intramuscular electrodes. The systems described previously fulfill the intramuscular electrode component. Designing a “surface-type” electrode that could be placed subcutaneously, either by small incision or percutaneous methods, would allow for the

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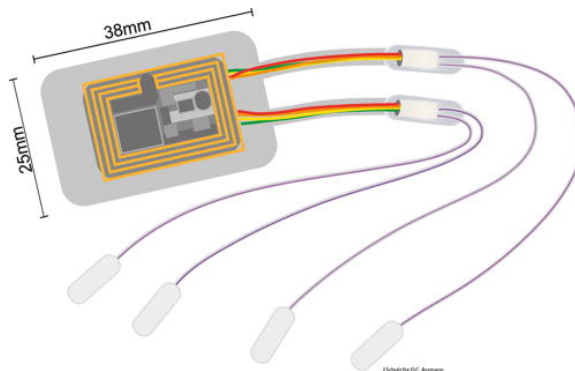


Figure 5.4: Implanted multichannel electrode for high-level amputees. The electrode demonstrated a high degree of biocompatibility and high fidelity of signal transduction in both rat and sheep models. The “tentacled” arrays allow for input from multiple muscles simultaneously.¹⁶

capture of global information similar to what surface electrodes do externally. A possible manifestation of these electrodes are imagined in Figure 5.5. These electrodes would be enclosed in flexible, biocompatible housing. The electrode ends are capable of reading a differential signal, such as with surface-based electrodes, and the differential could be modified to be between electrodes in the lateral or cranio-caudal direction, allowing for the determination of the best signal. Constructed as arrays of four electrode ends (two differential inputs), these units could be placed in either a circumferential manner at regular intervals or a patient-specific manner depending on residual anatomy. The head unit would provide wireless data and power transfer and serve as the reference signal for the two electrodes. Coupled with implantable intramuscular electrodes, or placed on top of sites of targeted reinnervation (discussed further), these electrodes help drive a prosthetic with global signal that is not subject to the skin electrode interface or sweat problems of typical surface electrodes. Addi-

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tionally, bypassing the subcutaneous layers significantly reduces the signal loss that may occur in the subcutaneous tissue due to high impedance and therefore makes detection of smaller currents possible.⁵⁴

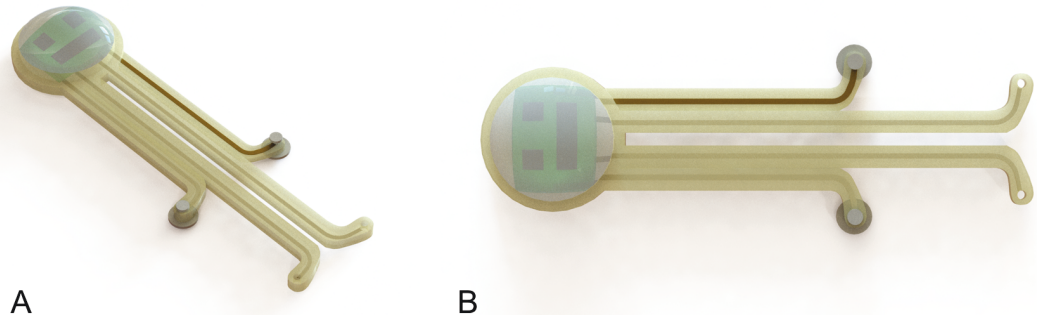


Figure 5.5: “Surface-like” electrodes that capture differential “global” inputs within the subcutaneous layer of the skin. The electrodes could be placed with a small incision and each would be capable of recording two differential inputs. The main body would house a wireless data and power transfer as well as the universal reference signal for the two electrodes.

5.3 Advanced Surgical Techniques

The advancement of prosthetics is inseparable from the advancement of surgical techniques surrounding amputation. The quality of the residual muscle and neural input ultimately drives overall EMG-based or peripheral nerve based control methods. Two methods in particular deserve special attention, as their increased usage will likely significantly alter the prosthetic control landscape.

5.3.1 Targeted Muscle Reinnervation

Targeted muscle reinnervation (TMR) refers to the reimplantation of nerves, whose original end target was a muscle that is now lost, into muscles that are still fully functional to serve as natural amplifiers of this biosignal.²⁹ The procedure has gained popularity to allow myoelectric prosthetic control for transhumeral amputees through the translocation of median, radial and musculoskeletal nerves to the pectoralis muscle.¹³⁰ Through this method, signals that would have been only minimally amplified by atrophied muscles can now be robustly increased through large, relatively superficial muscles. TMR uses the muscle as a natural amplifier, reducing the need to detect small, nerve-based signals. The results have been dramatic, with transhumeral amputees, for which no intrinsic muscles of the arm or forearm remain, controlling multiple simultaneous DOFs with virtual prosthetics.¹⁶¹ The apparent functional improvements have been so dramatic, it has led some to suggest the utility of this strategy at the time of amputation.¹⁶²

Expansion of TMR to the transradial population has the potential to improve EMG-based classification systems for this population as the available DOFs in prosthetics increase. Through “local” TMR, nerves from the residual stump could be reimplanted into nearby residual muscles in a directed manner at primary amputation. There would be minimal loss of nerve length, allowing for future hand transplantation if the patient is a candidate. Further, the method would likely accomplish similar reductions in postoperative neuroma pain as the traditional TMR procedure.¹⁶³

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Muscles such as FDP, FDS and EDC are large muscle beds, typically maintained in transradial amputees, that have distal attachments in the hand and therefore serve as excellent targets for local reinnervation. Implantation at the time of primary amputation could also prevent muscle atrophy in the postoperative period that would reduce the amplification properties of these muscles by offering a source of electrical activation. Finally, novel hybrid electrodes are being developed that can promote local nerve in-growth and could augment the response to “local” TMR.¹⁶⁴

5.3.2 Osseointegration

One factor contributing to poor prosthetic acceptance and usage rates involves the skin irritation and discomfort associated with wearing a prosthetic device for extended periods of time.³⁷ Much of this discomfort results from skin trauma due to harness or socket fit. Osseointegration arose in the sixties as a method of socket fixation that could combat many of these concerns.¹⁶⁵ And since its inception, it has expanded into transhumeral and transradial amputee use, using a two-stage process for implanting titanium fixtures into bone of the residual limb.¹⁶⁶ While improved socket comfort is indeed important, the true revolutionizing factor that I see for osseointegration is its role as a gateway to the inside of the residual limb.

The titanium fixture serves as the perfect conduit through which the signals from intramuscular or “surface-like” electrodes could be passed, foregoing the need for wireless data and power transfer. Research has already started exploring the possibility of

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a “osseointegrated human-machine gateway” that would allow for prosthetic fixation and signal conduction.⁹³ At one year post-implantation, the subject had no complications and demonstrated simultaneous control of three DOFs similar to able-bodied controls.⁹³ That patient also reports a some improved sensory feedback. Incorporation of novel electrodes, including combined surface and intramuscular electrodes, with osseointegration systems has the potential to dramatically restore functionality for patients who are candidates for the procedure, though concerns like infection risks and healing times should be considered before choosing osseointegration over other methods involving wireless, implantable systems.

5.4 Closing

The future of upper extremity prosthetics is currently marked by mechanical outpacing of computational abilities. In my opinion, this is a good problem to have. As computational abilities improve, novel algorithms will emerge and the ability to detect more subtle patterns will become a reality. When this happens, the prosthetics community will be ready, with highly advanced prosthetic limbs capable of mimicking natural movement. The responsibility of the clinicians, researchers and amputees involved in these rapid advances will be to critically evaluate the impact they have on the most important outcome, improvement of the quality of life of upper extremity amputees. To do so, combined results from subjective measurements and quantitative

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functional outcomes must be sought before new prosthetics or algorithms are considered “panaceas”. Likely, the answers to these questions will be patient-specific and it is our goal, as the research and clinical community, to find solutions that match the patient’s needs, rather than the reverse.

Appendix A

Classification Accuracy Tables

A.1 Overview

Classification accuracy for offline classification by pattern recognition with LDA require training on a particular subset of a dataset and then testing on a completely separate subset. Usually, the two subsets are complementary, such that their combination represents the entirety of the available data. In the circumstances of this research, in order to maximize the data used for training, data from $n - 1$ trials was used as the training subset, where n represents the total number of trials performed for a given set. Though this offers the highest level of training data, it can lead to decreased classification accuracies if one particular dataset is significantly different than the remainders. In this instance, the features may be averaged when it is included among other training datasets; however, when it is the sole set upon which training

APPENDIX A. CLASSIFICATION ACCURACY TABLES

data are tested, the discrepancy results in significant decreases in classification accuracy. Ultimately, the decision was made to include these error-prone datasets into the overall classification accuracy reported earlier in this document. However, within this appendix, there is the chance to review the impact such datasets may have had on classification accuracy.

For these data, the strong contraction dataset indicated as “Trial 1” represents the askew dataset. Removal of this dataset and recalculation reveals the following results:

	All Strong Contractions %	Strong with Trial 1 Removed %	p-value
sEMG	68.17	68.902	0.764
iEMG	57.96	61.459	0.421
sEMG + iEMG (all channels)	72.00	75.77	0.427
sEMG + iEMG (PT/Sup only)	68.75	71.32	0.495

Table A.1: Change in classification accuracy caused by removal of an erroneous dataset. From the p-values, it is reasonable to include this dataset in the overall average because the results do not significantly differ.

The results presented within the text of the thesis are the most accurate representation of the data. Removal of the ill-fitted dataset does not statistically alter classification accuracy. The data presented on the following pages are useful for indications of classification accuracy and determination of inter-trial variability.

Single Classifier
Strong Contractions

Training Data	1 2 3 4 5	1 2 3 4 6	1 2 3 5 6	1 2 4 5 6	1 3 4 5 6	2 3 4 5 6
Testing:	6	5	4	3	2	1
	Accuracy					
sEMG	75.94	75.11	70.27	68.61	62.1	64.59
iEMG	68.29	68.92	56.66	59.81	58.39	59.22
sEMG+iEMG	81.5	82	79.06	76.12	69.75	67.32
sEMG+iEMG	75.25	77.33	72.17	70.92	64.04	61.61

Strong Contractions

Training Data	1 2 3 4	1 2 3 5	1 2 4 5	1 3 4 5	2 3 4 5
Testing:	5	4	3	2	1
	Accuracy				
sEMG	73.55	60.71	66.32	71.82	60.85
iEMG	65.8	62.31	53.44	61.75	22.98
sEMG+iEMG	79.27	72.97	71.3	78.4	38.32
sEMG+iEMG	78.16	65.28	71.72	76.67	43.16

Moderate Contraction - Early

Training Data	1 2 3 4 5	1 2 3 4 6	1 2 3 5 6	1 2 4 5 6	1 3 4 5 6	2 3 4 5 6
Testing:	6	5	4	3	2	1
	Accuracy					
sEMG	81.9	83.45	68.43	73.83	78.26	79.47
iEMG	69.82	82.14	56.42	74.07	70.2	72.76
sEMG+iEMG	94.12	93.32	81.69	82.62	86.47	87.54
sEMG+iEMG	86.15	85.46	73.04	76.98	80.24	80.3

Moderate Contraction - Late

Training Data	1 2 3 4 5	1 2 3 4 6	1 2 3 5 6	1 2 4 5 6	1 3 4 5 6	2 3 4 5 6
Testing:	6	5	4	3	2	1
sEMG	72.59	75.01	70.72	75.22	81.55	70.54
iEMG	66.36	74.32	65.91	68.64	81.72	71.27
sEMG+iEMG	81.34	86.85	82.31	90.9	87.5	80.17
sEMG+iEMG	74.84	76.15	73.97	76.22	87.23	70.47

Parallel Classification
Moderate Normal

Training Data	1 2 3 4 5	1 2 3 4 6	1 2 3 5 6	1 2 4 5 6	1 3 4 5 6	2 3 4 5 6
Testing:	6	5	4	3	2	1
sEMG						
*DOF1	85.5	82.52	80.41	83.87	81.27	87.33
*DOF2	93.04	91.14	84.67	86.43	87.47	93.67
*DOF3	89.82	88.82	89.86	94.7	92	87.64
*Full Parallel	71.69	66.63	59.67	70.09	66.22	73.21
iEMG						
*DOF1	86.33	88.72	83.7	89.48	86.29	83.25
*DOF2	85.43	88.79	80.41	80.69	86.88	93.15
*DOF3	87.05	88.44	84.15	86.74	85.57	87.05
*Full Parallel	61.09	68.92	52.65	63.24	61.58	69.02
sEMG+iEMG (all channels)						
*DOF1	93.84	93.08	88.54	94.08	89.62	93.87
*DOF2	95.05	97.68	86.74	85.6	91.97	94.84
*DOF3	96.82	96.23	98.1	97.58	95.64	94.63
*Full Parallel	86.43	87.33	74.39	80.06	77.95	84.63
sEMG+iEMG (PT/Sup only)						
*DOF1	85.64	82.52	80.93	85.12	80.27	88.23
*DOF2	94.12	92.07	86.67	86.95	86.05	94.25
*DOF3	96.54	94.63	96.99	96.75	94.91	94.67
*Full Parallel	77.26	72.03	66.25	73.14	66.01	78.5

Parallel Classification

Moderate Late

Training Data	1 2 3 4 5	1 2 3 4 6	1 2 3 5 6	1 2 4 5 6	1 3 4 5 6	2 3 4 5 6
Testing:	6	5	4	3	2	1
sEMG						
*DOF1	78.64	87.95	71.93	86.57	85.12	77.36
*DOF2	92.38	84.39	90.41	87.57	89.65	88.16
*DOF3	90.24	89.96	93.67	96.02	94.25	91.28
*Full Parallel	64.73	66.87	60.02	72.52	70.89	59.61
iEMG						
*DOF1	82.1	95.26	81.41	90.41	87.05	81.52
*DOF2	85.88	86.47	83.9	79.96	89.34	78.61
*DOF3	83.35	92.45	88.75	79.82	94.22	93.01
*Full Parallel	60.16	76.05	59.95	58.91	72.93	59.67
sEMG+iEMG (all channels)						
*DOF1	85.12	97.99	84.63	91.87	87.92	91.73
*DOF2	94.63	90.27	94.43	87.92	93.42	85.88
*DOF3	95.29	97.58	98.79	96.92	98.89	98.51
*Full Parallel	78.44	86.99	78.75	79.23	80.86	77.4
sEMG+iEMG (PT/Sup only)						
*DOF1	77.12	87.68	71.24	84.91	85.91	75.46
*DOF2	91.69	84.74	90.03	87.37	90.17	87.68
*DOF3	95.02	97.44	98.13	98.48	98.27	98.51
*Full Parallel	67.57	72	61.58	74.21	75.18	63.62

Appendix B

Calculating Energy Expenditure

B.1 Energy Expenditure Considerations

The calculations used for energy expenditure of the limb during the functional assessment tests warrant some discussion. There are at least two factors that were not included in the calculations. The first main factor is drag caused by air friction. For a typical cylinder, this force would likely also be very small because the velocity of movement was well below the rate at which it typically becomes a factor. The second omission was the inertial energy of the the movement. This would be calculated by measuring the change in the kinetic energy of the movement:

$$KE = \frac{1}{2} * m * (V_{end} - V_{start})^2$$

APPENDIX B. CALCULATING ENERGY EXPENDITURE

For the course of the experiment, it was assumed that only at specific points, either nearing or leaving the target, would the velocity change significantly between measurements. Because each person altered their movements in a non-predictable manner, the time frame for each experience during which calculations of the kinetic energy would be useful was unclear. Therefore, it was elected to calculate only the change in potential energy between two data points, and to use this as the overall measure of energy. This may indeed underestimate the overall energy used during the experiment. Future work would be useful to determine the impact of movement velocity with a prosthetic to help clarify the impact of kinetic energy on the overall energy calculation.

Also important, the data were smoothed prior to all calculations with a minimum-order lowpass butterworth filter with stopband frequency of 22 Hz, after which there was 60 dB attenuation of the signal. This was applied to keep small fluctuations in the signal, which likely reflected noise instead of actual movements of the arm, to be removed prior to calculating the energy.

Listed below is the Matlab code corresponding to this calculation:

```
function EnergyExpended = energy(wt,xelbow,yelbow,zelbow,xhand,yhand,zhand)

%www.exrx.net/Kinesiology/Segments.html
%This website has all the data regarding mass of forearms and arms related
%to total weight. The numbers included below are the averaged for males and
%females.

% all weight measurements are % of total weight.
```

APPENDIX B. CALCULATING ENERGY EXPENDITURE

%Update: 3/28 to take out time part

```
massForearm = (.0172+.00575)*wt; %forearm + hand, bebionic3 = 525 g == 0.00725*wt
massArm = massForearm + (0.03075 * wt); %mass of whole arm
LengthArm = 28;
LengthForearm = 30;
ArmCOG = 0.447*LengthArm;
ForearmCOG = 0.432*LengthForearm;

explength = length(xhand);
EarmX = 0;
EarmY = 0;
EarmZ = 0;
PathhandX = zeros(1,explength);
PathhandY = zeros(1,explength);
PathhandZ = zeros(1,explength);
PatharmX = zeros(1,explength);
PatharmY = zeros(1,explength);
PatharmZ = zeros(1,explength);
%timebtwreadings = time/explength;

for i = 2:explength
    % quaternion in cm
    % W = F*D
    % F = mass*acceleration;
    % F = mass*distance/s^2;
    % In the case of z, we will just include the gravity component
    % for now.
    % For these measurements, we will disregard the drag force of the
    % air on the arm.
    %Therefore, the measurements are really only a function of moving
    %the weight of the arm a certain distance.
    PathhandX(i) = abs((xhand(i)-xhand(i-1))/100);
    PathhandY(i) = abs((yhand(i)-yhand(i-1))/100);
    PathhandZ(i) = abs((zhand(i)-zhand(i-1))/100);
    PatharmX(i) = abs((xelbow(i)-xelbow(i-1))/100);
    PatharmY(i) = abs((yelbow(i)-yelbow(i-1))/100);
    PatharmZ(i) = abs((zelbow(i)-zelbow(i-1))/100);

    EarmX = EarmX + PatharmX(i)*massArm*(9.8);%+((PatharmX(i)/timebtwreadings)
    EarmY = EarmY + PatharmY(i)*massArm*(9.8);%+((PatharmY(i)/timebtwreadings)
```

APPENDIX B. CALCULATING ENERGY EXPENDITURE

```
EarmZ = EarmZ + (zelbow(i)-zelbow(i-1))/100*massArm*9.8;

end
KEarm = EarmX + EarmY + EarmZ;
PathHand= sum(PathhandX) + sum(PathhandY) + sum(PathhandZ);

EnergyExpended(1,1) = KEarm;
EnergyExpended(1,2) = PathHand;
end
```

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Vita



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He has spent the last two years on sabbatical from his residency in order to complete his Masters of Science in Engineering from Johns Hopkins University. He won the George Wingfield Semmes award for Excellent Undergraduate Engineering student from Georgia Institute of Technology in 2006. He has additionally served as a research resident on the Surgical Oncology T32 Fellowship, during which time he explored novel diagnostic methods for intraoperative identification of cancer. His current research focuses on the use of intramuscular signals to improve simultaneous, multi-DOF control in prosthetics.

VITA

Robert will complete his General Surgery residency in 2018, after which time he will pursue a fellowship in Vascular Surgery.